同意書

編號 AS-IRB02-112154

NUM :

Date: 2023/05/03 日期

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

修訂日期 Revised Date: 1217' 2015

申請案編號 Application No: 計畫名稱 Project title:

AS-IRB01-17056 (R4)

台灣癌症登月計畫: 1. 發展新世代台灣癌症之精準醫療路徑圖(綱要計畫 一、台灣癌症登月計畫); 2. 重大疾病新穎治療開發-分項計畫五、多體 學智慧醫療

Taiwan Cancer Moonshot Project: 1. Next-generation Pathway of Taiwan Cancer Precision Medicine (Subjective Aim 1- Taiwan Cancer Moonshot Project); 2. Development of Novel Treatments for Major Diseases (Subproject 5 - Multiomic Big Data-based Intelligent Navigation System for Precision Oncology)

陳玉如 Yu-Ju Chen

申請人 Project Investigator:

合作機構 Collaborating Institute(s):

陳璿宇 / 統計科學研究所 Institute of Statistical Science

命志誠 Jyh-Cherng Yu / 三軍總醫院一般外科Department of Surgery, Division of General Surgery 陳晉興 Jin-Sing Chen / 台大醫學院醫學系外科部Department of Surgery, College of Medicine, National Taiwan University 國立臺灣大學醫學院附設癌醫中心醫院 National Taiwan University Cancer Center

俞松良 Sung-Liang Yu / 台大醫學院醫學檢驗暨生物技術學系Department of Clinical Laboratory Sciences and Medical Biotechnology, College of Medicine, National Taiwan University 楊泮池 Pan-Chyr Yang / 台大醫院內科部Department of Internal Medicine, College of Medicine, National Taiwan

University

張基晟 Gee-Chen Chang / 中山醫學大學附設醫院 肺癌診治研究中心 Chief of Lung Cancer treatment center, Chung Shan Medical University Hospital 徐國軒 Kuo-Hsuan Hsu / 臺中榮民總醫院 內科部 呼吸治療科 Division of Critical Care and Respiratory Therapy,

Department of Internal Medicine, Taichung Veterans General Hospital 賴鴻政 Hung-Cheng Lai / 臺北醫學大學醫學系 The College of Medicine of Taipei Medical University; 衛生福利部雙和醫院 婦產科 Obstetrics & Gynecology Ho Hospital, Ministry of Health and Welfare 吳明賢 Ming-Shiang Wu / 國立臺灣大學醫學院內科 Internal Medicine, National Taiwan University College of

Medicine

吳登強 Deng-Chyang Wu / 高雄醫學大學附設中和紀念醫院 胃腸內科 Division of Gastroenterology, Department of Internal Medicine, Kaohsiung Medical University Hospital

陳立宗 Li-Tzong Chen / 高雄醫學大學附設醫院 血液腫瘤內科 Hepatobiliary Division, Department of Internal Medicine, Kaohsiung Medical University Hospital

沈延盛 Yan-Shen Shan / 國立成功大學醫學院附設醫院 外科部 Department of Surgery, National Cheng Kung

University College of Medicine



執行期間 Project Duration: From 2018/01/23 to 2035/12/31

核准日期 Approval Date: 2023/05/03

有效期限 Due Date: From 2023/05/03 to 2035/12/31

進度或成果報告 Progress Report:

1. 請於 2024/01/22 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 IRB at Academia Sinica before 2024/01/22 for continuing

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 Progress reports are submitted to the Department of Health, a copy should be submitted to the IRB at Academia Sinica.

3. 如研究對象有不良反應或發生非預期事件,應即時向主管機關報告並副知本委員會。

All the adverse events or unanticipated problems are required to be reported to the official institute and IRB of Academia Sinica 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:

- 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 subjects, must be approved by the IRB of Academia Sinica.
- 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。

Amendments of an approved research protocol shall be submitted for IRB approval prior to its implementation. Where any research entity affiliated principal investigator or research personnel are subject to violate of that, the responsible ministry of central government may fine the research entity a penalty in the amount of no less than NT\$100,000 nor more than NT\$1,000,000, may terminate the research, and may publish the name of the research entity so penalized.

茲 證明上項醫學研究計畫(AS-IRB-BM-17056 v. 5),包括計畫書、研究對象說明同意書、問卷,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。

The above named study proposal (AS-IRB-BM-17056 v.5) has been reviewed, along with the informed consent form and questionnaire, and found to conform with the guidelines set forth by IRB on Biomedical Science Research / IRB-BM Academia Sinica.

