

同意書 編號 AS-IRB02-107029 NUM : 日期 2018/01/23 Date :	中央研究院醫學研究倫理委員會 研究計畫審查通過證明 <i>Certificate of Approval</i>	IRB02 修訂日期 Revised Date : 1217' 2015
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申請案編號 Application No : AS-IRB01-17051(N)

計畫名稱 Project title : 利用乳癌患者血液中之循環腫瘤細胞來發展早期乳癌偵測及術後診斷之臨床應用
Detection of circulating tumor cells in peripheral blood of breast cancer patients to develop the clinical application for early breast cancer detection and diagnostics

申請人 Project Investigator : 張瑛芝 Ying-Chih Chang

合作機構 Collaborating Institute(s):

陳訓徹 Shin-Cheh Chen / 長庚紀念醫院 一般外科及乳房外科 Department of General Surgery, Chang Gung Memorial Hospital

周旭桓 Hsu-Huan Chou / 長庚紀念醫院 一般外科及乳房外科 Department of General Surgery, Chang Gung Memorial Hospital

沈士哲 Shih-Che Shen / 長庚紀念醫院 一般外科及乳房外科 Department of General Surgery, Chang Gung Memorial Hospital

游啟昌 Chi-Chang Yu / 長庚紀念醫院 一般外科及乳房外科 Department of General Surgery, Chang Gung Memorial Hospital

執行期間 Project Duration: Recruitment from 2018/01/23 to 2020/12/31
; Follow-up until 2030/12/31

核准日期 Approval Date : 2018/01/23

有效期限 Due Date : From 2018/01/23 to 2030/12/31

進度或成果報告 Progress Report :

- 1.請於 2019/01/22 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 2019/01/22 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 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，應即時向主管機關報告並副知本委員會。
All the adverse events 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 :

- 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 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-17051 v.1)，包括計畫書、研究對象說明同意書，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。

The above named study proposal(AS-IRB-BM-17051 v.1) has been reviewed, along with the informed consent form, and found to conform with the guidelines set forth by IRB on Biomedical Science Research / IRB-BM Academia Sinica.