

2022 年第 10 次第一人體試驗委員會會議記錄

2022 year 10th-A IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2022 年 10 月 11 日（星期二）

二、時間 Time：12:00-13:00

三、地點 Location：蘭醫師大樓 B1 尊榮 B 廳 / Webex

四、主席 Chairperson：

蘇矢立（院內、醫療、醫師、男性）

Su, Shih-Li ( Affiliation with Institution, Medical Personnel ( Scientific member ), doctor, male )

出席人員 Attendant：(職稱略 omit title)

■ 陳書毓（院內、醫療、護理、女性）

Chen, Shu-Yu ( Affiliation with Institution, Medical Personnel ( Scientific member ), Nurse, female )

■ 楊淵博（院內、醫療、醫師、男性）

Yang, Yuan-Po ( Affiliation with Institution, Medical Personnel ( Scientific member ), doctor, male )

■ 林彥至（院內、醫療、醫師、男性）

Lin, Yen Chih ( Affiliation with Institution, Medical Personnel ( Scientific member ), doctor, male )

■ 賴穎萱（院內、醫療、藥師、女性）

Lai, Ying-Hsuan ( Affiliation with Institution, Medical Personnel ( Scientific member ), Pharmacist, female )

■ 柯智慧（院內、非醫療、社工、女性）

Ko, Chih-Hu ( Affiliation with Institution, Nonmedical Personnel ( non-Scientific member ), Social Worker, female )

■ 倪淑鳳（院外、非醫療、社會公正人士、女性）

Shu-Feng, Ni ( non-Affiliation with Institution, Nonmedical Personnel ( non-Scientific member ), Member of society, female )

■ 賴芳足（院外、醫療、公共衛生、女性）

Lai, Fang-Zu ( non-Affiliation with Institution, Medical Personnel ( Scientific member ), Epidemiology/Statistics, female )

■ 詹明真（院外、非醫療、法律、女性）【熟稔易受傷害族群-未成年人（18 至未滿 20 歲），法律專家】

Chan, Melody ( Affiliation with Institution ( Husband is CCH employee ), Nonmedical Personnel ( non-Scientific member ), Lawyer, female )

■ 林志榮（院外、醫療、公衛/統計、男性）

Lin, Jr-Rung Lin ( non-Affiliation with Institution, Medical Personnel ( Scientific member ), Epidemiology/ Statistics, male )

■ 林景釧 ( 院外、非醫療、社會人士、男性 )

Lin, Ching-Chuan ( non-Affiliation with Institution, Nonmedical Personnel ( non-Scientific member ), Member of society, male )

	人數	備註
醫療 Medical Personnel	7	醫師(3)、護理(1)、藥師(1)、公共衛生/統計(2)、 doctor (3) 、Nurse (1) 、Pharmacist (1) 、Epidemiology/ Statistics (2)
非醫療 Nonmedical Personnel	4	法律(1)、社工(1)、社會人士(2) Lawyer(1) 、Social Worker (1) 、Member of society (2)
科學 Scientific member	7	醫師(3)、護理(1)、藥師(1)、公共衛生/統計(2) doctor (3) 、Nurse (1) 、Pharmacist (1) 、Epidemiology/ Statistics (2)
非科學 non-Scientific member	4	法律(1)、社工(1)、社會人士(2) Lawyer(1) 、Social Worker (1) 、Member of society (2)
男 male	5	院內(3)、院外(2) Affiliation with Institution (3) 、non-Affiliation with Institution (2)
女 female	6	院內(3)、院外(3) Affiliation with Institution (4) 、non-Affiliation with Institution (2)

備註：Ⓐ 依據「人體研究法」第七條：審查會應置委員五人以上，包含法律專家及其他社會公正人士；研究機構以外人士應達五分之二以上；任一性別不得低於三分之一。審查會開會時，得邀請研究計畫相關領域專家，或研究對象所屬特定群體之代表列席陳述意見。According to Article 7 of the “Human Subjects Research Act:” “The IRB shall consist of five or more members, including legal expert and other persons of disinterested community members; more than two-fifths shall not be affiliated with the research entity; and no gender shall constitute less than one-third. During IRB meetings, the IRB may invite the attendance of experts familiar with the research field, or representatives of any appropriate group affiliated with the human subjects, to attend and provide comments.

Ⓑ 依據「人體研究倫理審查委員會組織及運作管理辦法」第六條：審查會召開一般程序審查會議時，其出席委員應包括機構外之非具生物醫學科學背景委員一人以上。五人以上，不足七人之審查會，應有三分之二以上之委員出席；七人以上之審查會，應有半數以上之委員出席，始得開會。出席委員均為單一性別時，不得進行會議。According to Article 6 of the “Standards and Operational Guidance for Ethics Review of Human Subject Research:” “Members present at routine review sessions should include at least

one with non-biomedical or science background. Two-thirds of entire member should be present for boards with more than 5 and less than 7 members; half of the entire member should be present for boards with more than 7 members before the meeting is commenced. The meeting may not be commenced if the attendee are of the same gender.”

列席人員 Presenting staff：(職稱略 omit title)

- 黃淑萍 (IRB 秘書) Ng Sock Ping (IRB secretary)
- 葉正吉 (IRB 行政人員) Yeh, Cheng Chi (IRB staff)
- 林巧芸 (IRB 行政人員) Lin, Ciao Yun (IRB staff)
- 洪翠霞 (IRB 行政人員) Hung, Tsui-Hsia (IRB staff)
- 李欣儀 (IRB 行政人員) Li, Hsin-Yi (IRB staff)

請 假 Leave：(職稱略 omit title)

- 蕭品卉 (院內、醫療、醫師、女性)

Hsiao, Yi-Hsuan (Affiliation with Institution, Medical Personnel (Scientific member), doctor, female)

缺 席 Absence：(職稱略 omit title)

記 錄 Recorder：洪翠霞 Hung, Tsui-Hsia

五、會議內容 Meeting：

主題	計畫名稱	決議
編號：220716 【新案 複審第 1 次】 主持人：彭于賓	玻尿酸組織填充前回抽-透過前置利多卡因針劑增加安全性	修正後複審
編號：201114 【期中報告第 2 次】 主持人：林聖皓	一項第二/第三期、隨機分配、雙盲、安慰劑對照試驗，在先前未曾接受治療的晚期非鱗狀非小細胞肺癌病患中，比較 TIRAGOLUMAB 合併 ATEZOLIZUMAB 加上 PEMETREXED 和 CARBOPLATIN/CISPLATIN 療法與 PEMBROLIZUMAB 加上 PEMETREXED 和 CARBOPLATIN/CISPLATIN 療法	修正後複審
編號：210702 【臨時動議】 主持人：林聖皓	一項隨機分組、第三期、開放性試驗，以患有轉移性鱗狀或非鱗狀非小細胞肺癌病人為對象，探討皮下給予 Pembrolizumab 相較於靜脈給予 Pembrolizumab，在併用含鉑類雙重化療作為第一線治療時的藥物動力學與安全性	追蹤病理部改善流程進度及實驗室檢體銷毀紀錄

(一) 已通過之初審案(簡易審查)Report the approved protocol by expedited review

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
1	220807	探討用餐滿意度項目與攝取量關係 Investigation the correlation of food service satisfaction and food ingestion in hospital	游欣亭 YU HSIN TING	(略) (N/A)	(略) (N/A)
2	220813	乳房攝影篩檢追蹤分析研究：以雲林地區為例 The mammography screening in Yunlin county: a retrospective study	黃倩慈 Huang Chien Tzu	(略) (N/A)	(略) (N/A)
3	220906	探討改良式皮瓣於修補面部傷口及術後重建之效果：回溯性研究 To investigate the effect of modified skin flaps in repairing facial wounds and reconstruction after surgery: a retrospective study	楊蕙如 Hui-Ju Yang	(略) (N/A)	(略) (N/A)
4	220921	以人工智慧預測子宮內膜癌之發生與復發 Application of artificial intelligence to predict the occurrence and recurrence of endometrial cancer.	吳東穎 WU DONG- YING	(略) (N/A)	(略) (N/A)

(二) 報告已核准之變更案(簡易審查)Report the approved amendment by expedited review

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
1	180907 【第 11 次】	一項第 3 期、開放性、隨機分配試驗，針對未接受 ESA 且需要輸注紅血球的受試者，以 IPSS-R 評估為極低、低或中等風險的骨髓增生不良症候群 (MDS) 引起之貧血，比較使用 Luspatercept (ACE-536) 相較於 Epoetin alfa 的療效及安全性 A PHASE 3, OPEN-LABEL, RANDOMIZED STUDY TO COMPARE THE EFFICACY AND SAFETY OF LUSPATERCEPT (ACE-536) VERSUS EPOETIN ALFA FOR THE TREATMENT OF ANEMIA DUE TO IPSS-R VERY LOW, LOW OR INTERMEDIATE RISK MYELODYSPLASTIC SYNDROMES (MDS) IN ESA NAIVE SUBJECTS WHO REQUIRE RED BLOOD CELL TRANSFUSIONS	林炫聿 Hsuan Yu Lin	(略) (N/A)	(略) (N/A)
2	181244	利用核磁共振擴散影像合成的虛擬彈性影	周成德	(略)	(略)

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
	【第 2 次】	像與真實核磁共振彈性影像評估肝臟纖維化的程度 Utility of diffusion weighted imaging (DWI) virtual elastography and MR Elastography in liver fibrosis assessment	ChenTe Chou	(N/A)	(N/A)
3	191236 【第 2 次】	卜邁維斯(Primovist)顯影之全肝動態造影對肝腫瘤偵測及鑑別的能力分析 Utility of Primovist-enhanced MRI with whole liver perfusion imaging in characterization of liver tumors	周成德 ChenTe Chou	(略) (N/A)	(略) (N/A)
4	200916 【第 3 次】	一項針對在亞洲接受 Bictegravir/ Emtricitabine/Tenofovir Alafenamide (B/F/TAF) 之 HIV-1 感染成人病患，評估有效性、安全性、依從性和健康相關生活品質的多國、非介入性、群組試驗 Multi-country, non-interventional, cohort study of the effectiveness, safety, adherence, and health-related quality of life in HIV-1 infected adult patients receiving Bictegravir/ Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in Asia	劉尊榮 Liu, Chun-Eng	(略) (N/A)	(略) (N/A)
5	210908 【第 3 次】	運用員工健康數據建構機器學習模型預測員工之心血管疾病風險與過負荷風險 Establishment of a machine learning model based on the employees' health database for cardiovascular disease and work overload risk prediction	劉晏孜 Yen Tze Liu	(略) (N/A)	(略) (N/A)
6	220103 【第 1 次】	治療中心性漿液性脈絡膜視網膜病變的長期結果分析 Long-term results for the treatment of non-resolving central serous chorioretinopathy	吳建昇 Wu Jian sheng	(略) (N/A)	(略) (N/A)

(三) 報告已核准之期中報告(簡易審查)Report the approved interim report by expedited review

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
1	200518 【第 2 次】	開發一種高特異性新冠病毒核酸恆溫增幅多樣性即時檢測平台 Development of real-time detection platform for the new coronavirus based on highly	古天雄 Ku Tien hsiung	(略) (N/A)	(略) (N/A)

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
		specific loop-mediated isothermal amplification (sLAMP)			
2	200916 【第 2 次】	一項針對在亞洲接受 Bictegravir/ Emtricitabine/Tenofovir Alafenamide (B/F/TAF) 之 HIV-1 感染成人病患，評 估有效性、安全性、依從性和健康相關生 活品質的多國、非介入性、群組試驗 Multi-country, non-interventional, cohort study of the effectiveness, safety, adherence, and health-related quality of life in HIV-1 infected adult patients receiving Bictegravir/ Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in Asia	劉尊榮 Liu, Chun-Eng	(略) (N/A)	(略) (N/A)
3	210813 【第 1 次】	居家照顧服務品質、服務成效及主要照顧 者照顧負荷之間的關聯 The relationship among the service quality, service effectiveness and primary caregiver burden in home care service	黃瑞華 Jui-Hua Huang	(略) (N/A)	(略) (N/A)

## (四) 報告已存查之結案報告 Report the final report for reference

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
1	201009	胸腔內科早期預警關鍵因素專案 Early Warning Sign Critical Factor Project for Chest Medicine	林聖皓 Sheng Hao Lin	(略) (N/A)	(略) (N/A)
2	211008	玻璃體內注射抗血管新生因子(aflibercept) 治療特發性視網膜血管炎、動脈瘤、視神 經視網膜炎綜合症之效果:病例報告 Idiopathic retinal vasculitis, aneurysms, and neuroretinitis (IRVAN) syndrome treated with Intravitreal injection of Aflibercept: a case report	吳建昇 Wu Jian sheng	(略) (N/A)	(略) (N/A)
3	211027	經歷未完整之雷射屈光角膜層狀重塑術後 角膜外凸之病例討論 Corneal ectasia after unsuccessful laser-assisted in situ keratomileusis (LASIK) with incomplete flap formation: a case report	吳建昇 Wu Jian sheng	(略) (N/A)	(略) (N/A)
4	211031	病例報告：巨細胞病毒網膜炎併發阻塞性 血管炎與治療後網膜斑塊的低清除率 Cytomegalovirus retinitis with occlusive	吳建昇 Wu Jian sheng	(略) (N/A)	(略) (N/A)

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
		vasculitis and the slow clear up rate of retinal lesions after treatment			
5	220328	臨床護理師之人格特質、工作氣氛與離職傾向相關因素之探討 The Study of Correlational Factors among Personality Traits, Working Atmospheres and Turnover Intentions on Bedside Registered Nurses.	賴以青 Yi-Ching Lai	(略) (N/A)	(略) (N/A)

## (五) 報告已存查之終止報告 Report the terminated protocol

序號	IRB 編號	計畫名稱	主持人	醫療主審	審查結果
1	200518	開發一種高特異性新冠病毒核酸恆溫增幅多樣性即時檢測平台 Development of real-time detection platform for the new coronavirus based on highly specific loop-mediated isothermal amplification (sLAMP)	古天雄 Ku Tien hsiung	(略) (N/A)	存查 File for reference
☞終止原因：研究技術這兩年已經變更，原技術將不使用。計畫申請時，幾次更改為標準檢體，不符研究利益。					
2	220422	以機器學習來預測肺炎病患 14 天內非預期性再入院風險 Machine Learning Model for Predicting 14-day unpredictable hospital readmission in patients with pneumonia	林俊維 Chun-Wei Lin	(略) (N/A)	存查 File for reference
☞終止原因：需大量資料收集，經資訊室提供，速度就為緩慢。故經小組討論，以置換 AI 主題。					

## (六) 報告已存查之暫停報告 Report the suspended protocol：(無 None)

## (七) 報告已存查之撤案報告 Report the withdraw protocol：(無 None)

## (八) 報告已核准之國衛院/ JIRB/ C-IRB/ NRPB Report the ratify protocol that was approved by NHRI/ JIRB/ C-IRB/ NRPB

序號 No.	IRB 編號 IRB No.	國衛院/ JIRB/ C-IRB/ NRPB 編號	階段次數	主持人 PI
		NHRI/ JIRB/ C-IRB/ NRPB protocol No.	Stage	
計畫名稱 Protocol title				
1	220812	【CIRB】110CIRB08184	新案 複審第 2 次	夏建勳 Chien Hsun Hsia

	一項樞紐第三期隨機分組、安慰劑對照的臨床試驗，評估鳥甘酸環化西每(sGC)刺激劑 Vericiguat/MK-1242 用於治療射出低收縮分率之慢性心臟衰竭成人的療效與安全性 A Pivotal Phase 3 Randomized, Placebo-controlled Clinical Study to Evaluate the Efficacy and Safety of the sGC Stimulator Vericiguat/MK-1242 in Adults With Chronic Heart Failure With Reduced Ejection Fraction			
2	220821	【CIRB】111CIRB01015	新案 複審第 1 次	林聖皓 Sheng Hao Lin
	針對罹患不具可行動基因體改變的晚期或轉移性非小細胞肺癌 (NSCLC) 患者，將 Sacituzumab Govitecan 合併療法用於第一線治療的一項開放標記、多中心、第二期試驗 An Open-label, Multicenter, Phase 2 Study of Sacituzumab Govitecan Combinations in First-line Treatment of Patients with Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC) Without Actionable Genomic Alterations			
3	181111	【CIRB】107CIRB02016	變更案第 12 次 初審	賴鴻文 Hung Wen Lai
	一項第三期、多中心、隨機分配、開放標示試驗，在可手術之三陰性乳癌患者中，比較 ATEZOLIZUMAB (抗 PD-L1 抗體) 併用以 ANTHRACYCLINE/TAXANE 類為主的輔助性化療與單獨的化學治療 A PHASE III, MULTICENTER, RANDOMIZED, OPEN-LABEL STUDY COMPARING ATEZOLIZUMAB (ANTI-PD-L1 ANTIBODY) IN COMBINATION WITH ADJUVANT ANTHRACYCLINE/TAXANE-BASED CHEMOTHERAPY VERSUS CHEMOTHERAPY ALONE IN PATIENTS WITH OPERABLE TRIPLE-NEGATIVE BREAST CANCER			
4	200614	【CIRB】109CIRB03040	變更案第 6 次 初審	林進清 Jin-Chin Lin
	針對先前接受過免疫檢查點抑制劑治療之患有復發性或轉移性頭頸部鱗狀細胞癌的受試者，接受 Monalizumab 或安慰劑併用 Cetuximab 的一項第三期、隨機分配、雙盲、多中心、全球性試驗 A Phase 3 Randomized, Double-blind, Multicenter, Global Study of Monalizumab or Placebo in Combination With Cetuximab in Participants With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck Previously Treated With an Immune Checkpoint Inhibitor			
5	211009	【CIRB】110CIRB03046	變更案第 4 次 初審	莊智鈞 Chih Chun Chuang
	一項第 IIIb 期、全球性、多中心、隨機分配、視力評估人員設盲試驗，針對以植入型儲藥器系統給予 Ranibizumab 的 36 週充填療程在新生血管型老年性黃斑部病變病患的療效、安全性與藥物動力學(VELODROME) A PHASE IIIb, GLOBAL, MULTICENTER, RANDOMIZED, VISUAL ASSESSOR-MASKED STUDY OF THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF A 36-WEEK REFILL REGIMEN FOR THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (VELODROME)			
6	211009	【CIRB】110CIRB03046	變更案第 3 次 初審	莊智鈞 Chih Chun Chuang



	<p>一項第 IIIb 期、全球性、多中心、隨機分配、視力評估人員設盲試驗，針對以植入型儲藥器系統給予 Ranibizumab 的 36 週充填療程在新生血管型老年性黃斑部病變病患的療效、安全性與藥物動力學(VELODROME)</p> <p>A PHASE IIIb, GLOBAL, MULTICENTER, RANDOMIZED, VISUAL ASSESSOR-MASKED STUDY OF THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF A 36-WEEK REFILL REGIMEN FOR THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (VELODROME)</p>			
7	211010	【CIRB】110CIRB03048	變更案第 3 次 初審	莊智鈞 Chih Chun Chuang
	<p>一項多中心、開放性的延伸試驗，針對新生血管型老年性黃斑部病變病患評估以植入型儲藥器系統給予 Ranibizumab 的長期安全性與耐受性(PORTAL)</p> <p>A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY AND TOLERABILITY OF THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (PORTAL)</p>			
8	180913	【CIRB】107CIRB03035	期中報告第 4 次 複審第 1 次	林聖皓 Sheng Hao Lin
	<p>一項針對腫瘤為 EGFR 突變具 TKI 抗藥性之轉移性非鱗狀細胞非小細胞肺癌(NSCLC)受試者，比較 Pemetrexed + 含鉑化療合併或未合併 Pembrolizumab (MK-3475)治療的隨機分配、雙盲、第三期試驗 (KEYNOTE-789)</p> <p>A Randomized, Double-Blind, Phase 3 Study of Pemetrexed + Platinum Chemotherapy with or without Pembrolizumab (MK-3475) in TKI-resistant EGFR-mutated Tumors in Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) Participants (KEYNOTE-789)</p>			
9	191102	【CIRB】108CIRB08134	期中報告第 3 次 初審	賴冠銘 KuanMing Lai
	<p>Erdaftinib 用於晚期實體腫瘤且 FGFR 基因改變的受試者之一項第二期試驗</p> <p>A Phase 2 Study of Erdaftinib in Subjects with Advanced Solid Tumors and FGFR Gene Alterations</p>			
10	201019	【CIRB】109CIRB08138	期中報告第 2 次 複審第 1 次	王文甫 Wenfu Wang
	<p>一項開放性、多中心、持續試驗，評估患有阿茲海默症之參與者長期接受 GANTENERUMAB 的安全性、耐受性和療效</p> <p>AN OPEN-LABEL, MULTICENTER, ROLLOVER STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND EFFICACY OF LONG-TERM GANTENERUMAB ADMINISTRATION IN PARTICIPANTS WITH ALZHEIMER'S DISEASE</p>			