

2020 年第 9 次第二人體試驗委員會會議記錄

2020 year 9th-B IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2020 年 09 月 18 日（星期五）

二、時間 Time：12:21-13:46

三、地點 Location：福懋大樓 B1 尊榮 B 廳

四、主席 Chairperson：

葉坤土(院內、醫療、醫師、男性)

Yeh, Kun-Tu (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

出席人員 Attendant：(職稱略 omit title)

■ 楊爵閣(院內、醫療、統計、男性)

Yang, Chueh Ko (Affiliation with Institution, Medical Personnel (Scientific member), statistics, male)

■ 陳琬青(院內、醫療、醫師、女性)

Chen, Wan-Chin (Affiliation with Institution, Medical Personnel (Scientific member), doctor, female)

■ 楊淵博(院內、醫療、醫師、男性)

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

■ 蔡玉娟(院內、醫療、藥師、女性)

Tsai, Yu-Chuan (Affiliation with Institution, Medical Personnel (Scientific member), Pharmacist, female)

■ 黃柔婷(院內、非醫療、社工背景、女性)

Hwang, Rour-Ting (Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Social Worker, female)

■ 劉柏毅(院內、醫療、醫師、男性)

Liu, Po-I (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

■ 謝雅惠(院外、醫療、社會人士、女性)

Hsieh, Ya-Hui (non-Affiliation with Institution, Medical Personnel (Scientific member), Member of society, female)

■ 陳志東(院外、非醫療、社會人士、男性)

Chen, Chih-Tung (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, male)

- 林倩芸(院外、非醫療、法律專業、女性)
Lin, Chien Yun (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Law, female)
- 王復堯(院外、非醫療、社會人士、男性)
Wang, Fu-Yan (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, male)
- 李吉豐 (院外、非醫療、病友團體代表、男性)
Lee, Chi-Fong (Affiliation with Institution (Wife is CCH employee), Nonmedical Personnel (non-Scientific member), Patient group representative, male)

	人數	備註
醫療 Medical Personnel	7	醫師(4)、藥師(1)、統計(1)、社會人士(1) doctor (4) , Pharmacist (1) , Statistics (1), Member of society(1)
非醫療 Nonmedical Personnel	5	社會人士(3)、法律(1)、病友團體代表(1) Member of society (3) , Law(1), Patient group representative(1)
科學 Scientific member	7	醫師(4)、藥師(1)、統計(1)、社會人士(1) doctor (4) , Pharmacist (1) , Statistics (1), Member of society(1)
非科學 non-Scientific member	5	社會人士(3)、法律(1)、病友團體代表(1) Member of society (3) , Law(1), Patient group representative(1)
男 male	7	院內(4)、院外(3) Affiliation with Institution (5) , non-Affiliation with Institution (2)
女 female	5	院內(3)、院外(2) Affiliation with Institution (3) , non-Affiliation with Institution (2)

備註 Remarks :

- ① 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.”

- ② 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)

- 葉正吉 Yeh, Cheng Chi (IRB staff)
- 林巧芸 Lin, Ciao Yun (IRB staff)
- 洪翠霞 Hung, Tsui-Hsia (IRB staff)
- 李欣儀 Li, Hsin-Yi (IRB staff)

請 假 Leave：(職稱略 omit title)

缺 席 Absence：(職稱略 omit title)

記 錄 Recorder：林巧芸 Lin, Ciao Yun

五、會議內容 Meeting：

(一) 討論議案 (議案主題及決議) Discussion (theme and decision)

主題	計畫名稱	決議
編號：200833 【新案】 主持人：林晏任	在急診使用氧氣治療缺氧的病患—安全性與舒適度分析	修正後提會
編號：190506 【變更案第 3 次】 主持人：紀炳銓	一項開放性、多中心延伸和長期觀察性試驗，對象為先前曾參與由 GENENTECH 和/或羅氏大藥廠委託之 ATEZOLIZUMAB 試驗的患者	核准
編號：150802 【期中報告第 5 次】	探討台灣女性乳癌患者基因與治療前後表現相關性	修正後複審

主持人：林喆		
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(二) 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	200713	探討台灣地區之單一醫學中心回溯多發性骨髓病人骨髓檢體的基因報告與歐美國家預後的差異性 This study is to investigate to analyze clinical prognosis differences of multiple myeloma patients between in Taiwan and Europe and America in a single medical center.	曾若涵 Ruo-Han Tseng	(略) (N/A)	(略) (N/A)
2	200714	單一醫學中心回溯 Regorafenib 藥物在末期大腸直腸癌患者的治療效果、併發症和無症狀存活期、整體存活期等分析 A single medical center reviewed the drug regorafenib in the treatment of stage IV colorectal cancer patients, treatment effect, side effect, asymptomatic survival, overall survival and other analysis.	曾若涵 Ruo-Han Tseng	(略) (N/A)	(略) (N/A)
3	200723	急性失能(腦中風、髖關節骨折)個案出院後之復健選擇分析 Analysis of rehabilitation options for acute disability patients after discharge	黃素猜 Huang Su Tsai	(略) (N/A)	(略) (N/A)
4	200729	探討術後血清鉀離子和鎂離子濃度對接受心臟擇期手術患者預後之影響。 Influence of postoperative serum potassium and magnesium concentrations on outcomes of patients undergoing elective cardiac surgery.	高曼靈 KAO MAN LING	(略) (N/A)	(略) (N/A)
5	200731	外科加護病房運用組合式照護之導尿管泌尿道感染密度之成效 The effectiveness of urinary catheter bundle care. A single center experiences.	林幸君 LIN Hsing Chun	(略) (N/A)	(略) (N/A)
6	200812	局部晚期直腸癌患者接受前導性/確定性放化療之預後、預測因子分析 Analysis of outcome and prognostic factors of preoperative chemoradiotherapy/definitive chemoradiotherapy for locally advanced rectal cancer	林振斌 JhenBin Lin	(略) (N/A)	(略) (N/A)
7	200827	影像導航胸腔鏡手術進行延伸性肺節切除術 Extended segmentectomy for small lung nodule with image-guided video-assisted	王秉彥 Wang Bing Yen	(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
		thoracoscopic surgery			

(三) 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	161006 【第 5 次】	腦中風病人住院臨床路徑之實施以促進醫療照護品質 Implementation of Clinical Pathway to Improve Quality of Healthcare in Stroke Inpatients	魏大森 TaSen Wei	(略) (N/A)	(略) (N/A)
2	200515 【第 1 次】	評估兩種劑量的 Tofacitinib 與一種腫瘤壞死因子抑制劑 (TNFi) 用於類風濕性關節炎受試者的第 3B/4 期隨機分配安全性指標試驗 PHASE 3B/4 RANDOMIZED SAFETY ENDPOINT STUDY OF 2 DOSES OF TOFACITINIB IN COMPARISON TO A TUMOR NECROSIS FACTOR (TNF) INHIBITOR IN SUBJECTS WITH RHEUMATOID ARTHRITIS	田雅之 YaChih Tien	(略) (N/A)	(略) (N/A)
3	200609 【第 1 次】	頭頸癌患者之相關危險因子探討 The predisposing factors of the incidence and survival rate of head and neck cancer	劉晏孜 Yen Tze Liu	(略) (N/A)	(略) (N/A)

(四) 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	091237 【第 9 次】	整合性跨團隊預防跌倒之成效 Effects of an Integrated Transdisciplinary Program for Fall Prevention in Hospitalized Patients	魏大森 Ta-Sen WEI	(略) (N/A)	(略) (N/A)
2	180816 【第 2 次】	探討更年期婦女之血管舒縮症、粒線體及代謝疾病的相關性 Relationships of vasomotor symptoms, mitochondria, and metabolism-related disorders in menopausal women	吳鴻明 Hung Ming Wu	(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
3	190814 【第 1 次】	困難消化道病變之診斷及治療: 單一中心之經驗 Diagnosis and treatment of difficult GI disease: Review of A single center experience	顏旭亨 HsuHeng Yen	(略) (N/A)	(略) (N/A)

(五) 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	150912	急性腎損傷病患者發炎及氧化壓力相關蛋白(如氧化物還原酶)在腎臟上的表現與臨床上預後的關聯性 Association between renal expressions of inflammatory and redox proteins (such as peroxiredoxins) and renal clinical outcomes in patients with acute kidney injury	吳家麟 Wu Chialin	(略) (N/A)	(略) (N/A)
2	170605	肺癌病患粒線體基因變異和氧化壓力變化之研究探討 Investigation of mitochondrial genetic variation and oxidative stress in the lung cancer patients	王秉彥 Wang Bing Yen	(略) (N/A)	(略) (N/A)
3	191116	老人便秘與自覺健康狀況之初探 Exploring the constipation and self-perceived health status of the elderly	黃毅玲 Yi Ling Huang	(略) (N/A)	(略) (N/A)

(六) 報告已存查之終止報告 Report the terminated protocol (無)

(七) 報告已存查之暫停報告 Report the suspended protocol (無)

(八) 報告已存查之撤案報告 Report the withdraw protocol (無)

(九) 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 NHRI/ JIRB/ C-IRB/ NRPB protocol No.	階段次數 Stage	主持人 PI
計畫名稱 Protocol title				

1	200802	【CIRB】109CIRB05082	新案 複審第 1 次	林炫聿 Hsuan Yu Lin
<p>一項第三期、隨機分配、開放標記、有效療法對照的多中心試驗，針對目前已接受補體抑制劑治療的成人和青少年陣發性夜間血紅素尿症 (PNH) 患者，評估 CROVALIMAB 相較於 ECULIZUMAB 的療效及安全性</p> <p>A Phase III, Randomized, Open-label, Active-controlled, Multicenter Study Evaluating the Efficacy and Safety of CROVALIMAB Versus ECULIZUMAB In Adult and Adolescent Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) Currently Treated with Complement Inhibitors</p>				
2	200803	【CIRB】109CIRB05083	新案 複審第 1 次	林炫聿 Hsuan Yu Lin
<p>一項第三期、隨機分配、開放標記、有效療法對照的多中心試驗，針對先前未接受補體抑制劑治療的成人和青少年陣發性夜間血紅素尿症 (PNH) 患者，評估 CROVALIMAB 相較於 ECULIZUMAB 的療效及安全性</p> <p>A Phase III, Randomized, Open-label, Active-controlled, Multicenter Study Evaluating the Efficacy and Safety of CROVALIMAB Versus ECULIZUMAB In Adult and Adolescent Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) Not Previously Treated with Complement Inhibitors</p>				
3	200809	【CIRB】109CIRB05070	新案 複審第 1 次	田雅之 Ya-Chih Tien
<p>一項多中心、隨機、雙盲、安慰劑對照、平行分組的試驗，針對患有中度至重度活動性全身性紅斑性狼瘡受試者，評估 dapirolizumab pegol 療效及安全性</p> <p>A multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of dapirolizumab pegol in study participants with moderately to severely active systemic lupus erythematosus</p>				
4	200820	【CIRB】109CIRB06093	新案 複審第 1 次	蘇維文 Wei Wen Su
<p>評估使用 GSK3228836 治療慢性 B 型肝炎病毒的受試者之療效與安全性的第 IIb 期多中心、隨機分配、部分盲性、平行組試驗 (B-Clear)</p> <p>Phase IIb Multi-Center, Randomised, Partial-Blind Parallel Cohort Study to Assess the Efficacy and Safety of Treatment with GSK3228836 in Participants with Chronic Hepatitis B Virus (B-Clear)</p>				
5	170323	【CIRB】106CIRB01008	變更案第 7 次 初審	顏旭亨 HsuHeng Yen
<p>第 3 期、雙盲、隨機分配、安慰劑對照的組合試驗，在罹患中度至重度活動性克隆氏症的受試者中，評估 Filgotinib 在誘導與維持緩解上的療效及安全性</p> <p>Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease</p>				
6	180211	【CIRB】106CIRB10146	變更案第 8 次 初審	王文甫 Wenfu Wang
<p>一項第 III 期、多中心、隨機分配、雙盲、安慰劑對照、平行分組，探討 GANTENERUMAB 使用於早期(前驅期至輕度)阿茲海默症病患的療效和安全性試驗</p> <p>A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP, EFFICACY, AND SAFETY STUDY OF GANTENERUMAB IN PATIENTS WITH EARLY(PRODROMAL TO MILD) ALZHEIMER'S DISEASE</p>				
7	180706	【CIRB】107CIRB02021	變更案第 5 次 初審	林炫聿 Hsuan-Yu Lin

在罹患復發型或難治型慢性淋巴球性白血病且帶有 17p 缺失的受試者中探討 Venetoclax 療效的第 2 期開放式試驗 A Phase 2 Open-Label Study of the Efficacy of Venetoclax in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia in the Presence of 17p Deletion			
8	181022	【CIRB】107CIRB07106	變更案第 3 次 初審 林炫聿 Hsuan Yu Lin
一項第二期、多中心、開放標記、隨機分配試驗，針對曾接受 imatinib 治療，但未達深層分子反應之慢性骨髓性白血病慢性期 (CML-CP) 患者，比較 imatinib 合併口服 asciminib、持續使用 imatinib、改為使用 nilotinib 等療法的成效 A Phase 2, multi-center, open-label, randomized study of oral asciminib added to imatinib versus continued imatinib versus switch to nilotinib in patients with CML-CP who have been previously treated with imatinib and have not achieved deep molecular response			
9	190321	【CIRB】107CIRB12196	變更案第 7 次 初審 杜思德 Tu shih te
一項隨機分配、第 3 期、開放標示試驗，比較 LY3298176 相較於調整劑量之胰島素 Degludec 對第 2 型糖尿病病患血糖控制的影響(SURPASS-3) A Randomized, Phase 3, Open-Label Trial Comparing the Effect of LY3298176 versus Titrated Insulin Degludec on Glycemic Control in Patients with Type 2 Diabetes (SURPASS-3)			
10	190607	【CIRB】107CIRB01014	變更案第 5 次 初審 林聖皓 Sheng Hao Lin
RESILIENT: 在接受含鉑第一線療法期間或之後疾病已惡化的小細胞肺癌病患中，比較 irinotecan 微脂體注射劑 (ONIVYDE) 與 topotecan 的隨機分配、開放標示、第 3 期試驗 RESILIENT: A Randomized, Open Label Phase 3 Study of Irinotecan Liposome Injection (ONIVYDER) versus Topotecan in Patients with Small Cell Lung Cancer Who Have Progressed on or after Platinum-based First-Line Therapy			
11	200615	【CIRB】109CIRB02015	變更案第 1 次 初審 王文甫 Wenfu Wang
第三 b 期、開放標示、多中心、評估 BIIB037 (aducanumab) 用於先前參加過 Aducanumab 221AD103, 221AD301, 221AD302 和 221AD205 試驗的阿茲海默症受試者之安全性試驗 Phase 3b open-label, multicenter, safety study of BIIB037 (aducanumab) in subjects with Alzheimer's disease who had previously participated in the Aducanumab studies 221AD103, 221AD301, 221AD302 and 221AD205			
12	190914	【CIRB】108CIRB06107	期中報告第 1 次 初審 王全正 ChuanCheng Wang
在先前未治療的局部晚期或轉移性膽道癌病患中，比較 NUC-1031 加上 cisplatin 與 gemcitabine 加上 cisplatin 的一項第三期、開放標示、多中心、隨機分配試驗 A Phase III Open-Label, Multi-Centre, Randomised Study Comparing NUC-1031 plus Cisplatin to Gemcitabine plus Cisplatin in Patients with Previously Untreated Locally Advanced or Metastatic Biliary Tract Cancer			
13	181016	【CIRB】107CIRB08121	終止 初審 顏旭亨 HsuHeng Yen
一項隨機分配、雙盲、安慰劑對照的第二期試驗，在罹患中度至重度活動性發炎性腸道疾病的成年男性中，評估 Filgotinib 對睪丸的安全性 A Randomized, Double-blind, Placebo-controlled Phase 2 Study to Evaluate the Testicular Safety of Filgotinib in Adult Males with Moderately to Severely Active Inflammatory Bowel Disease			

