

2021 年第 9 次第二人體試驗委員會會議記錄

2021 year 9th-B IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2021 年 09 月 24 日（星期五）

二、時間 Time：12:30-13:18

三、地點 Location：福懋大樓 B1 尊榮 B 廳

四、主席 Chairperson：

劉森永(院內、醫療、醫師、男性)

Liu, Sen-Yung ( 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 )

■ 陳彥宇(院內、醫療、醫師、男性) 【IRB 210508、180816 利益迴避-同科醫師  
IRB 210508、180816 Avoiding conflicts of interest- Physician of the same  
department】Chen, Yen-Yu ( Affiliation with Institution, Medical Personnel ( Scientific  
member ), doctor, male )

■ 林逸祥(院內、醫療、藥師、男性)

Lin, Yi-Hsiang ( Affiliation with Institution, Medical Personnel ( Scientific member ), Pharmacist, male )

■ 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 )

■ 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	6	醫師(3)、藥師(1)、統計(1)、社會人士(1) doctor (3) , 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	6	醫師(3)、藥師(1)、統計(1)、社會人士(1) doctor (3) , 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(3)、院外(4) Affiliation with Institution (4) , non-Affiliation with Institution (3)
女 female	4	院內(2)、院外(2) Affiliation with Institution (2) , 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)

- 黃淑萍 Ng Sock Ping ( IRB secretary )
- 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)

- 劉柏毅(院外、醫療、醫師、男性)

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

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：210508 【變更案第 1 次 複審第 1 次】 主持人：吳劭彥 PI: Wu Shao Yen	比較頭皮/耳針與傳統體針對於帕金森患者療效影響。	核准 Approved

<p>編號：180816  <b>【期中報告第 3 次】</b>          主持人：吳鴻明          PI: Hung Ming Wu</p>	<p>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</p>	<p>核准 Approved</p>
<p>編號：190914  <b>【期中報告第 2 次】</b>          主持人：王全正          PI: Chuan Cheng Wang</p>	<p>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</p>	<p>修正後複審          Minor revisions required</p>
<p>編號：210321  <b>【結案 複審第 1 次】</b>          簡易審查          主持人：陳賢孟          PI: Hsien- Meng Chen</p>	<p>台灣中部成人 A 型肝炎盛行率調查</p>	<p>存查，同意試驗繼續進行 File, agree on continue the trial</p>
<p>編號：200820  <b>【不遵從事件】</b>          2021-08-18 初始          試驗偏差          202108-13          主持人：蘇維文          PI: Wei Wen Su</p>	<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>存查，同意試驗繼續進行 File, agree on continue the trial</p>
<p>編號：210321  <b>【不遵從事件】</b>          2021-08-17 初始          試驗偏差</p>	<p>台灣中部成人 A 型肝炎盛行率調查</p>	<p>存查，同意試驗繼續進行 File, agree on continue the trial</p>

202108-11 主持人：陳賢孟 PI: Hsien- Meng Chen		
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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	210708	癌症精準醫療及生物資料庫整合平台合作 示範計畫 Cancer Precision Medicine and Biobank Consortium Collaboration Pilot Project	林慶雄 Ching Hsiung Lin	(略) (N/A)	(略) (N/A)
2	210719	胸腔 X 光之結節偵測人工智慧輔助系統模 型開發 Chest X ray nodule AI assisted detection model development	黃國揚 Kuo-Yang Huang	(略) (N/A)	(略) (N/A)
3	210803	脈衝振盪儀器與傳統肺功能在支氣管擴張 劑測試陽性之間的關聯性-回溯性研究 Correlation between impulse oscillometry and traditional lung function in positive bronchodilator response - Retrospective Study	林聖皓 Sheng Hao Lin	(略) (N/A)	(略) (N/A)
4	210808	比較組織細菌培養及肋膜積液培養對於膿 胸的敏感性 Pleural peels tissue culture and pleural fluid culture for empyema	王秉彥 Wang Bing Yen	(略) (N/A)	(略) (N/A)
5	210809	COVID-19 通報個案於急診之流行病學與 預後分析 Epidemiological and prognostic analysis of COVID-19 reported cases in emergency department	林晏任 Lin Yan Ren	(略) (N/A)	(略) (N/A)
6	210817	以人工智慧輔助診斷胸部外傷之電腦斷層 影像 Application of artificial intelligence to assist CT diagnosis of thoracic trauma	黃章倫 Chang Lun Huang	(略) (N/A)	(略) (N/A)

## (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	191227 【第 3 次】	健康檢查大數據資料庫建立暨健康風險預 測模式分析及精準個人健康管理之應用 The establishment of the health examination	劉晏孜 Yen Tze Liu	(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
		database for big data analytics and risk prediction model, and the application of personalized precision healthcare			
2	210626 【第 1 次】	骨髓腔和骨髓內釘直徑差異對以骨髓內釘治療之股骨幹骨折癒合時間的影響 Does nail diameter or canal-nail difference really affect union time after intramedullary nailing of femoral shaft fracture?	石久煜 Chiu Yu Shih	(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	150913 【第 6 次】	乳癌臨床全人照護計畫相較於傳統乳癌照護於乳癌患者對於生理、心理、靈性及社會層面多面向評估 Compare CCPC breast cancer care program with conventional breast cancer care program in breast cancer patients in physical, psychological, spiritual and social aspects	賴鴻文 Hung Wen Lai	(略) (N/A)	(略) (N/A)
2	160809 【第 5 次】	曾經接受過 Sofosbuvir 為基礎之無干擾素療法之慢性 C 型肝炎病患其肝臟及肝外表徵長期預後之追蹤研究 Long-term hepatic and extra-hepatic outcomes of CHC patients post sofosbuvir-based IFN-free treatment (LONGHEAD study)	徐友春 Yu Chun Hsu	(略) (N/A)	(略) (N/A)
3	180709 【第 3 次】	一項第 2/3 期、隨機分配、雙盲、安慰劑和活性對照、平行分組、多中心試驗計畫，評估 Guselkumab 使用於中度至重度活動性克隆氏症參與者的療效和安全性 A Phase 2/3, Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn's Disease	顏旭亨 HsuHeng Yen	(略) (N/A)	(略) (N/A)
4	200823 【第 1 次】	血液腫瘤科住院病人跌倒高危險群下床給予防跌措施與預防跌倒之成效 Investigation and analysis of the effect of fall	陳明玲 Ming-ling Chen	(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
		prevention in hospitalized patients with hematological oncology			
5	200834 【第 1 次】	消化系疾病之長期服藥遵從度調查：單一中心之經驗 Drug compliance in GI disease: a single center experience	顏旭亨 HsuHeng Yen	(略) (N/A)	(略) (N/A)
6	200912 【第 1 次】	給予非酒精性脂肪肝患者介入營養衛教後改善脂肪肝之情形 Nutrition interventions for the treatment of non-alcoholic fatty liver disease in adults	蔡玲貞 Ling Jane Tsai	(略) (N/A)	(略) (N/A)
7	201010 【第 1 次】	以生物標誌檢測模組預測慢性肝炎之進展 Predict the progress of chronic hepatitis with biomarker modules of detected values.	胡美黛 Mei-Tai Hu	(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	160316	大腸癌患者之葡萄糖代謝缺失 Rab11 及 CA8 等相關基因及腸道菌相表現之臨床關連 Clinical correlation of Gut microbiota and Rab11 and CA8 expression in human colorectal cancer with impaired glucose metabolism.	蘇維文 Wei Wen Su	(略) (N/A)	(略) (N/A)
2	181263	胎兒治療患者的病因學探討和預後 The etiology and prognosis of fetus who underwent fetal therapy.	吳琬如 WanJu Wu	(略) (N/A)	(略) (N/A)
3	191015	老年人急診就醫與使用潛在不適當藥品 (Beers Criteria) 之相關性探討。 Association between potentially inappropriate medication (Beers criteria) and emergency department visits among the elderly	黃淑萍 Ng Sock Ping	(略) (N/A)	(略) (N/A)
4	200407	介人員工健康促進成效 Intervene in the effectiveness of employee health promotion	陳佳琳 CHEN CHIA LIN	(略) (N/A)	(略) (N/A)
5	200415	哺餵母乳自主性量表之發展與信效度檢驗 Development and Investigation of Validity and Reliability of the Maternal Breastfeeding Autonomy Scale	賴詩茜 LAI SHIH CHIEN	(略) (N/A)	(略) (N/A)
6	201002	孕婦與伴侶實際接種流感疫苗之預測因	李心慈	(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
		素：多中心追蹤研究 Predictors of receiving flu vaccine among pregnant couples: Multi-center cohort study	Hsin- Tzu Li	(N/A)	(N/A)

(六) 報告已存查之終止報告 Report the terminated protocol (無 None)

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

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

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

序號	IRB 編號	國衛院/JIRB/ C-IRB/NRPB 編號	階段次數	主持人	計畫名稱
1	190315	【CIRB】108CIRB01004	變更案第 7 次 初審	顏旭亨 HsuHeng Yen	針對患有晚期肝細胞癌而未曾接受先前全身性抗癌療法之受試者，研究 Cabozantinib (XL184) 併用 Atezolizumab 相較於 Sorafenib 的一項隨機分配對照第 3 期試驗 A Randomized, Controlled Phase 3 Study of Cabozantinib (XL184) in Combination with Atezolizumab versus Sorafenib in Subjects with Advanced Hepatocellular Carcinoma Who Have Not Received Previous Systemic Anticancer Therapy
2	200209	【CIRB】107CIRB09149	變更案第 4 次 初審	林聖皓 Sheng Hao Lin	一項第三期、雙盲、安慰劑對照、國際多中心試驗，針對可手術切除之第二期及第三期非小細胞肺癌(NSCLC)患者，評估使用前導性/輔助性 Durvalumab 治療的療效 (AEGEAN) A Phase III, Double-blind, Placebo controlled, Multi-center International Study of Neoadjuvant/adjuvant Durvalumab for the Treatment of Patients with Resectable Stages II and III Non-small Cell Lung Cancer (AEGEAN)
3	200615	【CIRB】109CIRB02015	變更案第 3 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
4	200725	【CIRB】109CIRB03044	變更案第 5 次 初審	蘇維文 Wei Wen Su	一項在患有慢性 B 型肝炎感染的參加者中，評估 VTP-300 併用或不併用 Nivolumab 的安全性、耐受性及免疫原性的第 1b/2a 期開放標示試驗 A Phase 1b/2a, Open-Label Study to Evaluate the Safety, Tolerability and Immunogenicity of VTP-300 with or without Nivolumab in Participants with Chronic Hepatitis B infection



5	200802	【CIRB】109CIRB05082	變更案第 3 次 初審	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 Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) Currently Treated with Complement Inhibitors</p>				
6	200803	【CIRB】109CIRB05083	變更案第 3 次 初審	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 Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) Not Previously Treated with Complement Inhibitors</p>				
7	200820	【CIRB】109CIRB06093.1	變更案第 5 次 初審	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>				
8	200903	【CIRB】109CIRB04069	變更案第 5 次 初審	賴冠銘 KuanMing Lai
<p>在曾接受造血細胞移植 (HCT) 且經證實發生呼吸道融合病毒 (RSV) 上呼吸道感染 (URTI) 的成年受試者中，評估 RV521 治療之安全性、耐受性及療效的隨機、雙盲、安慰劑對照試驗</p> <p>Randomized, double-blind, placebo-controlled trial of the safety, tolerability, and efficacy of RV521 in the treatment of adult subjects who have undergone hematopoietic cell transplantation (HCT) with a documented upper respiratory tract infection (URTI) with respiratory syncytial virus (RSV)</p>				
9	201119	【CIRB】109CIRB07123	變更案第 4 次 初審	陳守棟 SHOU TUNG CHEN
<p>一項第 II 期、隨機分配、開放性、多中心試驗，針對曾接受治療之雌激素受體陽性、HER2 陰性局部晚期或轉移性乳癌的病患，評估 GDC-9545 相對於醫師選擇的內分泌單一療法的療效和安全性</p> <p>A PHASE II, RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF GDC-9545 COMPARED WITH PHYSICIAN'S CHOICE OF ENDOCRINE MONOTHERAPY IN PATIENTS WITH PREVIOUSLY TREATED ESTROGEN RECEPTOR-POSITIVE, HER2-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER</p>				
10	210312	【CIRB】109CIRB11220	變更案第 3 次 初審	徐友春 Yu Chun Hsu

<p>一項探討 BR11-835 (VIR-2218)和 BR11-179 (VBI-2601)合併療法用於治療慢性 B 型肝炎病毒 (HBV)感染之安全性和療效的第 2 期、多中心、隨機分配、開放性試驗</p> <p>A Phase 2 Multicenter, Randomized, Open-label Study to Investigate the Safety and Efficacy of BR11-835 (VIR-2218) and BR11-179 (VBI-2601) Combination Therapy for the Treatment of Chronic Hepatitis B Virus (HBV) Infection</p>				
11	210622	【CIRB】110CIRB3054	變更案第 1 次 初審	邱南英 Nan Ying Chiu
<p>針對持續接受試驗 54135419TRD3013 的 Esketamine 鼻用噴霧治療之難治型重度憂鬱症患者所進行的開放性長期延伸試驗</p> <p>Open-label Long-Term Extension Study for Participants with Treatment-Resistant Major Depressive Disorder Who are Continuing Esketamine Nasal Spray Treatment From Study 54135419TRD3013</p>				
12	170904	【CIRB】106CIRB04073	期中報告第 4 次 複審第 1 次	紀炳銓 Bin Chuan Ji
<p>全球性第三期、隨機分配、多中心、開放標記、含對照的臨床試驗，評估 Durvalumab 或 Durvalumab 加上 Tremelimumab 併用含鉑化療，做為轉移性非小細胞肺癌 (NSCLC) 患者的第一線治療 (POSEIDON)</p> <p>A Phase III, Randomized, Multi-Center, Open-Label, Comparative Global Study to Determine the Efficacy of Durvalumab or Durvalumab and Tremelimumab in Combination With Platinum-Based Chemotherapy for First-Line Treatment in Patients With Metastatic Non Small-Cell Lung Cancer (NSCLC) (POSEIDON)</p>				