

2021 年第 6 次第三人體試驗委員會會議記錄

2021 year 6th-C IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2021 年 06 月 24 日（星期四）

二、時間 Time：12:00-14:05

三、地點 Location：福懋大樓 B1 尊榮 B 廳

四、主席 Chairperson：

張櫻霖（院內、醫療、醫師、男性）【IRB170705 利益迴避-主持人為三親等內之姻親、IRB180712 利益迴避-協同主持人為三親等內之姻親 IRB 170705 Avoiding conflicts of interest- PI is the third degree affined relationship. IRB 180712 Avoiding conflicts of interest- co-PI is the third degree affined relationship】

Chang, Ing-Lin (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

出席人員 Attendant：(職稱略 omit title)

- 陳彥宇(院內、醫療、醫師、男性)【IRB 200710 利益迴避-同科醫師 IRB 200710 Avoiding conflicts of interest- Physician of the same department】

Chen, Yen Yu (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

- 高峻凱（院內、醫療、醫師、男性）

Kao, Jun-Kai (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

- 倪亭淵(院內、醫療、醫師、女性)

Ni, Ting-Yuan (Affiliation with Institution, Medical Personnel (Scientific member), doctor, female)

- 高小玲（院內、醫療、公衛/統計、女性）

Kao, Hsiao-Ling (Affiliation with Institution, Medical Personnel (Scientific member), Member of society, female)

- 蔡忠融（院外、醫療、公衛/統計、男性）

Tsai, Chung-Jung (non-Affiliation with Institution, Medical Personnel (Scientific member), Epidemiology/ Statistics, male)

- 洪婉純（院內、非醫療、社工、女性）【熟稔易受傷害族群-未成年人（18 至未滿 20 歲），社工師】

Hung, Wan-Chun (Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Social Worker, female)

- 陳明鋒(院內、非醫療、法律專業、男性)

Chen, Ming-Fong (Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Law, male)

- 蔡佩凌（院外、醫療、藥師、女性）
Tsai, Pei-Ling (non-Affiliation with Institution, Medical Personnel (Scientific member), Pharmacist, female)
- 張玉龍（院外、非醫療、社會公正人士、男性）
Chang, Yu-Lung (non-Affiliation with Institution, Nonmedical Personnel (Scientific member), Member of society, male)
- 蕭玲玲（院外、非醫療、家庭主婦、女性）
Hsiao, Ling-Ling (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, female)
- 吳姿慧(院外、非醫療、家庭主婦、女性)
Wu, Tzu-Hui (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, female)

| | 人數 Persons | 備註 Remark |
|---------------------------------|---------------|--|
| 醫療 Medical Personnel | 7 | 醫師(4)、藥師(1)、統計(2) Doctor (4), Pharmacist (1), Statistics (2) |
| 非醫療 Nonmedical Personnel | 5 | 社工(1)、法律(1)、社會公正人士(3) Social Worker (1), Law (1), Member of society (3) |
| 科學 Scientific member | 8 | 醫師(4)、藥師(1)、統計(2)、社會公正人士(1) Doctor (4), Pharmacist (1), Statistics (2), Member of society (1) |
| 非科學 non-Scientific member | 4 | 社工(1)、法律(1)、社會公正人士(2) Social Worker (1), Law (1), Member of society (2) |
| 男 Male | 6 | 院內(4)、院外(2) Affiliation with Institution (4), non-Affiliation with Institution (2) |
| 女 Female | 6 | 院內(3)、院外(3) Affiliation with Institution (3), non-Affiliation with Institution (3) |

備註：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。

Remark: (According to Article 7 of Human Body Research Law, the review board shall comprise of at least 5 board members, including legal experts and

other impartial citizens. More than two-fifths of the board members shall be persons not affiliated with the research institution and either of the genders shall not account for less than one-third of the board. Experts in the field related to the study protocol or representatives of the special population in the study shall be invited to attend review board meetings and voice their opinions.

- 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。
- ② According to Article 6 of “The Organization and Operation of Human Research Ethics Review Board,” attendees of the general board meetings shall include more than 1 board member who is not affiliated with the institution and who does not have biomedical background. For review boards of more than 5 members and less than 7 members, more than two-thirds of the members shall attend the meetings. For review boards of more than 7 members, the meeting shall only start if more than half of the members are present. If all the attendees are of the similar gender, the meeting shall not be conducted.

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)

缺 席 Absence：(職稱略 omit title)

記 錄 Recorder：洪翠霞 Hung, Tsui-Hsia

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：210201 【新案 複審第 1 次】 | 於加護病房中利用基礎胰島素合併連續靜脈胰島素治療高血糖急症 | 修正後複審 |

| | | |
|---|--|-------------|
| 主持人：毛羿傑 | | |
| 編號：210607 【新案】 主持人：游欣亭 | 米糠對非酒精性脂肪肝疾病飲食輔助治療效果 | 修正後複審 |
| 編號：170204 【變更案第 9 次】 主持人：賴鴻文 | PALLAS：Palbociclib 合作輔助試驗：一項針對患有賀爾蒙受體陽性（HR+）/第二型人類表皮生長因子受體（HER2）-陰性早期乳癌使用 Palbociclib 合併標準內分泌輔助治療和單用標準內分泌輔助治療的隨機分組、第 III 期試驗 | 核准 |
| 編號：170705 【期中報告第 4 次】 主持人：林慶雄 | 在罹患非鱗狀非小細胞肺癌的受試者中探討 ONO-4538 的第三期、多中心、隨機、雙盲試驗 | 修正後複審 |
| 編號：180712 【期中報告第 3 次】 主持人：林聖皓 | 一項針對分期 AJCC/UICC 第 8 版 II-III A 及 IIIB (T > 5cm N2) 完全切除 (R0) 之非小細胞肺癌 (NSCLC) 成年受試者，評估 canakinumab 相較於安慰劑做為輔助療法之療效及安全性的第三期、多中心、隨機分配、雙盲、安慰劑對照試驗 | 修正後複審 |
| 編號：200404 【期中報告第 1 次】 主持人：蔡俊傑 | 運用頭皮針及耳針進行針刺對於第 4,5 期慢性腎臟病患者之療效。 | 修正後複審 |
| 編號：200405 【期中報告第 1 次】 主持人：張明裕 | 運用頭皮針/耳針進行針刺對於兒童急性腦炎患者之療效 | 核准 |
| 編號：200613 【期中報告第 1 次】 主持人：溫永頌 | 發展以群組為基礎之客觀結構式教學評量教案建置及信效度分析 | 修正後複審 |
| 編號：200710 【期中報告第 1 次】 主持人：王文甫 | 發展阿茲海默失智症病人成年子女的整合性生物標記 | 修正後複審 |
| 編號：190906 【不遵從事件】 202106-2 主持人：顏旭亨 | 一項第三期、隨機分配、安慰劑對照、雙盲、多中心試驗，評估以 Etrasimod 作為中度至重度活動型潰瘍性結腸炎受試者誘導和維持治療的療效與安全性 | 存查，同意試驗繼續進行 |
| 編號：200804 【不遵從事件】 202106-1 主持人：陳清埤 | 一項第三期、前瞻性、多中心、雙盲、隨機、平行分組試驗，用於比較 2 mg Pitavastatin/ 10 mg Ezetimibe 與 Pitavastatin 和 Ezetimibe 對於原發性高膽固醇血症或混合血脂異常患者的療效和安全性 | 存查，同意試驗繼續進行 |

(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 | 210409 | 護理人員照顧 COVID-19 病患的壓力源與復原力相關 The stressors and resilience of nursing staff caring for COVID-19 patients | 陳淑純 SHU-CHUN CHEN | (略) (N/A) | (略) (N/A) |
| 2 | 210421 | 視網膜剝離引起黃斑部裂孔的病患接受手術後的視力預後及風險因子的討論 Outcome on the visual prognosis and risk factor of RRD induced macular hole patient after surgery | 陳珊霓 San Ni Chen | (略) (N/A) | (略) (N/A) |
| 3 | 210423 | 使用機器學習來預測慢性腎臟病患發生高血鉀之機會 Predict hyperkalemia in CKD patients using machine learning | 吳家麟 Wu Chialin | (略) (N/A) | (略) (N/A) |
| 4 | 210430 | 對晚期頭頸癌患者使用劑量調整之誘導化療之回溯性研究 Dose-modified Docetaxel plus Platinum based induction chemotherapy followed by de-intensified treatment for advanced head and neck cancer | 余萬年 YU WAN NIEN | (略) (N/A) | (略) (N/A) |
| 5 | 210504 | 環境衍生性有機氣膠對疾病負擔與社會負擔的影響：台灣地區之系統回顧與綜合解析(一、二) The impact of ambient secondary organic aerosol on the disease burden and social burden: A systematic review and meta-analysis in Taiwan (I, II) | 梁正中 Jeng-J ong Liang | (略) (N/A) | (略) (N/A) |
| 6 | 210509 | 探討與建立急性腎損傷病患使用腎臟替代療法之臨床預後的預測模型 Evaluation and development a prognosis predictive model in acute kidney injury patient with Renal-Replacement Therapy | 許秋婷 Chew Teng Kor | (略) (N/A) | (略) (N/A) |
| 7 | 210517 【免審】 | 芹黃素對體外培養人類子宮頸癌細胞 p53 蛋白在轉錄後修飾的調節作用 The regulatory effect of apigenin on the post-transcriptional modification of p53 protein in vitro cultured human cervical cancer cells | 楊爵閣 Yang Chueh Ko | (略) (N/A) | - |
| 8 | 210604 【免審】 | 探討 Methoxyhispolon methylether 之抗三陰性乳癌效應暨其機制 Study on the anti-Triple-negative breast cancer effect and the underlying mechanisms of Methoxyhispolon methylether | 廖志斌 LIAO CHIH PIN | (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 | 170204 【第 8 次】 | PALLAS : Palbociclib 合作輔助試驗：一項針對患有賀爾蒙受體陽性 (HR+) / 第二型人類表皮生長因子受體 (HER2)-陰性早期乳癌使用 Palbociclib 合併標準內分泌輔助治療和單用標準內分泌輔助治療的隨機分組、第 III 期試驗 PALLAS: PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer | 賴鴻文 Hung Wen Lai | (略) (N/A) | (略) (N/A) |
| 2 | 180823 【第 5 次】 | 一項第 3 期、多中心、隨機分配、雙盲、平行分組、在常規治療失敗及生物製劑治療失敗的中度至重度活動性潰瘍性結腸炎病患使用 Mirikizumab 的安慰劑對照誘導試驗 LUCENT 1 A Phase 3, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Induction Study of Mirikizumab in Conventional-Failed and Biologic-Failed Patients with Moderately to Severely Active Ulcerative Colitis LUCENT 1 | 顏旭亨 HsuHeng Yen | (略) (N/A) | (略) (N/A) |
| 3 | 190502 【第 3 次】 | 乳癌脈診分析：脈診可偵測乳癌放化療造成心血管之損傷 The analysis of radial pulse wave on breast cancer: Radial pulse can detect the injury of cardiac function causing by chemotherapy and radiotherapy. | 李佳穎 Chia ying Lee | (略) (N/A) | (略) (N/A) |
| 4 | 200331 【第 2 次】 | 以高擬真模擬情境於臨床醫護人員進行臨床急救能力和醫療團隊資源管理之學習成效 Learning effectiveness of emergency and critical care capability and team resource management in medical and nursing staff with high-fidelity simulation. | 李雅文 YA WEN LEE | (略) (N/A) | (略) (N/A) |
| 5 | 200514 【第 2 次】 | 以病人為師進行新冠肺炎敘事醫學教育之前驅研究 Practice narrative medical education on COVID-19 disease by using “patients as educators”: a pilot study | 侯俊成 Mark Chun Cheng Hou | (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 |
|-----------|-------------------|---|------------------------|--|---|
| 6 | 201110 【第 2 次】 | 對帶有抑制因子的 A 型或 B 型血友病受試者，評估皮下給藥之 Marzeptacog Alfa (活化型) 於視需要治療和出血事件控制之療效及安全性的第三期試驗： Crimson 1 試驗 Phase 3 Study to Evaluate the Efficacy and Safety of Subcutaneous Marzeptacog Alfa (Activated) For On-Demand Treatment and Control of Bleeding Episodes in Subjects with Hemophilia A or Hemophilia B, with Inhibitors: The Crimson 1 Study | 沈銘鏡 Ming Ching Shen | (略) (N/A) | (略) (N/A) |
| 7 | 201233 【第 1 次】 | 粒線體品質管控調節 MERRF 病人細胞的粒線體 DNA 突變之研究 Study on the mitochondrial quality control in the modulation of mitochondrial DNA mutation in the MERRF-derived culture cells | 魏耀揮 Yau Huei Wei | (略) (N/A) | (略) (N/A) |
| 8 | 201234 【第 1 次】 | 利用病人誘導性多功能幹細胞分化之皮質神經元探討粒線體疾病之神經系統損傷及其在粒線體標靶治療中的應用 Studies on the neurological disorder in mitochondrial encephalomyopathies using patient iPSCs-derived cortical neurons and its application in mitochondrial targeting therapy | 吳雨亭 Yu Ting Wu | (略) (N/A) | (略) (N/A) |
| 9 | 210302 【第 1 次】 | 一項開放性、非試驗性藥品、多中心、導入試驗，目的為在對應的治療性第 3 期基因療法試驗前，以腺相關病毒(AAV)載體-Spark100 (Benegene-1) 中和抗體陰性之中重度至重度 B 型血友病成人參與者 (FIX:C?2%)及腺相關病毒載體 6 (AAV6) 中和抗體陰性之中重度至重度 A 型血友病成人參與者 (FVIII:C?1%)，評估第九凝血因子 (FIX) 或第八凝血因子 (FVIII) 預防性替代療法在一般照護之下的前瞻性療效和選定的安全性資料 AN OPEN-LABEL, NON-INVESTIGATIONAL PRODUCT, MULTI-CENTER, LEAD-IN STUDY TO EVALUATE PROSPECTIVE EFFICACY AND SELECTED SAFETY DATA OF CURRENT FACTOR IX(FIX)OR FACTOR VIII(FVIII)PROPHYLAXIS | 沈銘鏡 Ming Ching Shen | (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 |
|-----------|-------------------|---|-----------|--|---|
| | | REPLACEMENT THERAPY IN THE USUAL CARE SETTING OF MODERATELY SEVERE TO SEVERE ADULT HEMOPHILIA B PARTICIPANTS(FIX:C?2%) WHO ARE NEGATIVE FOR NEUTRALIZING ANTIBODIES TO ADENO-ASSOCIATED VIRUS VECTOR-SPARK100(BENEGENE-1)AND MODERATELY SEVERE TO SEVERE HEMOPHILIA A ADULT PARTICIPANTS(FVIII:C?1%)WHO ARE NEGATIVE FOR NEUTRALIZING ANTIBODIES TO ADENO-ASSOCIATED VIRUS VECTOR 6(AAV6), PRIOR TO THE RESPECTIVE THERAPEUTIC PHASE 3 GENE THERAPY STUDIES | | | |

(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 | 140707 【第 7 次】 | 巴金森氏症病人輕度認知功能缺損的評估工具之比較 Comparison the screening tool for mild cognitive impairment patients with Parkinson's disease | 巫錫霖 Wu Shey Lin | (略) (N/A) | (略) (N/A) |
| 2 | 180802 【第 3 次】 | 重大外傷病人在心跳停止之復甦後期併發症分析 Analyzing the post-resuscitation complications in survivors from traumatic out-of-hospital cardiac arrest | 林晏任 Lin Yan Ren | (略) (N/A) | (略) (N/A) |
| 3 | 180810 【第 3 次】 | 腹膜透析患者的發炎指標和臨床預後之間的關係 The relationship between inflammatory indexes and clinical outcomes in peritoneal dialysis patients | 謝堯棚 Yao Peng Hsieh | (略) (N/A) | (略) (N/A) |
| 4 | 190708 【第 2 次】 | 停經前賀爾蒙陽性乳癌患者接受 GnRHa 皮下針劑注射患者疼痛指數分析及使用局部皮膚麻醉凝膠塗抹止痛效果評估 Pain evaluation for Premenopausal hormone | 賴鴻文 Hung Wen Lai | (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 |
|-----------|-------------------|--|---------------------|--|---|
| | | receptor positive breast cancer patients, who received GnRHα subcutaneous injection, and evaluate the analgesia effect of topical xylocaine jelly. | | | |
| 5 | 200401 【第 1 次】 | 進階護理人員工作滿意度之探討 A Study of Job Satisfaction among Advanced Practice Nurses | 蕭伊婷 Hsiao I Ting | (略) (N/A) | (略) (N/A) |
| 6 | 200416 【第 1 次】 | 急診護理人員歷經暴力事件後內心之衝擊與離職意念 Emergency nurses' psychological shock and intention to quit after experiencing violence. | 林倖如 LIN SHING JU | (略) (N/A) | (略) (N/A) |
| 7 | 200727 【第 1 次】 | 到院前心跳停止之兒童經急救能長期存活者其預後及併發症分析 Analysis of prognosis and complications of long-term survivors with pediatric out-of-hospital cardiac arrest | 林晏任 Lin Yan Ren | (略) (N/A) | (略) (N/A) |
| 8 | 200728 【第 1 次】 | 急診室致命性急性血管水腫(critical angioedema)之誘發因子分析 Risk factors associated with the occurrence of critical angioedema in the emergency department | 林晏任 Lin Yan Ren | (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 | 150609 | 停經之血管舒縮症狀對身體、心理及社會的衝擊 Physical and Psychosocial burden of vasomotor symptoms in menopause | 吳鴻明 Hung Ming Wu | (略) (N/A) | (略) (N/A) |
| 2 | 180109 | 台灣妊娠糖尿病盛行率和妊娠糖尿病對孕產婦和嬰兒結果的影響 Prevalence of gestational diabetes among Taiwanese and the impact of gestational diabetes on maternal and neonatal outcomes | 陳育正 Chen Yu Cheng | (略) (N/A) | (略) (N/A) |
| 3 | 180822 | 一項第 3 期、多中心、隨機分配、雙盲、平行分組，在中度至重度活動性潰瘍性結腸炎病患中探討 Mirikizumab 的安慰劑對照維持試驗 LUCENT 2 A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Arm, Placebo-Controlled Maintenance Study of | 顏旭亨 HsuHeng 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-Medic al primary reviewer |
|-----------|-------------------|--|----------------------------|--|--|
| | | Mirikizumab in Patients with Moderately to Severely Active Ulcerative Colitis LUCENT 2 | | | |
| 4 | 180823 | 一項第 3 期、多中心、隨機分配、雙盲、平行分組、在常規治療失敗及生物製劑治療失敗的中度至重度活動性潰瘍性結腸炎病患使用 Mirikizumab 的安慰劑對照誘導試驗 LUCENT 1 A Phase 3, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Induction Study of Mirikizumab in Conventional-Failed and Biologic-Failed Patients with Moderately to Severely Active Ulcerative Colitis LUCENT 1 | 顏旭亨 HsuHeng Yen | (略) (N/A) | (略) (N/A) |
| 5 | 181218 | 針對以胰島素皮下注射治療之住院個案，使用連續性血糖監測評估床邊血糖檢測的臨床效力 Using continuous glucose monitoring to evaluate the clinical validity of point-of-care bedside glucose testing in hospitalized patients treated with subcutaneous insulin therapy | 林世鐸 ShiDou Lin | (略) (N/A) | (略) (N/A) |
| 6 | 181222 | 針對住院病人以皮下胰島素注射治療，使用連續性血糖監測評估住院病人餐前血糖監測時間與胰島素注射時間及用餐時間的差距，是否會影響飯後及下一餐前的血糖值數值。 Using continuous glucose monitoring to evaluate the timing of insulin administration, glucose monitoring, and meal delivery. | 郭仁富 Jeng Fu Kuo | (略) (N/A) | (略) (N/A) |
| 7 | 190408 | 探討單一中心女性頭頸癌特徵 Characteristics Among Female Patients With Head and Neck Cancer- Single center study | 蔡國陽 Tsai Kuo Yang | (略) (N/A) | (略) (N/A) |
| 8 | 190908 | 台灣地區血清中尿酸濃度與衰弱症風險的關聯性 Association between uric acid level and risk of frailty – a nation-wide community-based study (HALST cohort) | 劉晏孜 Yen Tze Liu | (略) (N/A) | (略) (N/A) |
| 9 | 200124 | 探討 3-6 歲構音障礙兒童口腔吸吮習慣與構音錯誤類型之相關研究 The investigation of the relationship between oral sucking habits and types of articulation errors in children with articulation disorders | 顏向嬋 Hsiang- Chan 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-Medic al primary reviewer |
|-----------|-------------------|---|----------------------|--|--|
| | | aged 3-6 years. | | | |
| 10 | 200512 | 學前發展遲緩兒童構詞覺識與詞彙能力關係之研究 A Study on the Relationship between morphological Awareness and Vocabulary Ability of Children with Preschool Development Delay | 賴玫君 LAI, MEI-JYUN | (略) (N/A) | (略) (N/A) |
| 11 | 200709 | “太豪生醫”肺部電腦斷層 CAD 系統之臨床驗證 Clinical Evaluation of “TaiHao” LUNG-CT CAD System | 何上芸 Shang Yun Ho | (略) (N/A) | (略) (N/A) |

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

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

| 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 | 審查結果 Review result |
|--|-------------------|---|-----------------------|--|--------------------------|
| 1 | 190312 | 穴位按壓對改善臨床護理師的慢性肩頸痠痛及失眠之成效評估。 Efficacy assessment of Acupressure on clinical nurse with chronic neck pain and insomnia. | 黃頌儼 Sung Yen Huang | (略) (N/A) | 存查 File for reference |
| <p>☞終止原因：展延後第一次期中報告初審，皆已完成期中報告申請要件(個案收案表、利益衝突表)，但因計畫主持人的 GCP 教育時數今年(2021)剛好過期，且因部主任業務繁忙及防疫業務增多，無暇去上課補充 GCP 時數，故因 PI 之 GCP 時數不足無法通過期中報告之申請，決定終止本研究計畫。</p> | | | | | |
| 2 | 200817 | 穿戴裝置於個案健康管理之應用: 以減重及肺阻塞為例 The use of wearables in health management: taking bariatric and COPD as example | 王秉彥 Wang Bing Yen | (略) (N/A) | 存查 File for reference |
| <p>☞終止原因：因研究計畫中，提供智慧衣進行研究之廠商(俱揚)，至今尚未取得 TFDA 之判定，針對受試者安全疑慮問題，討論後決定終止此項收案。</p> | | | | | |

(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 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 | 210505 | 【CIRB】109CIRB10203 | 新案 複審第 1 次 | 楊郁 Yu Yang |
| 一項在有腎功能逐漸喪失風險之 A 型免疫球蛋白 (IgA) 腎病變患者中探討 Atrasentan 的第 3 期、隨機分配、雙盲、安慰劑對照試驗 (ALIGN 試驗) A Phase 3, Randomized, Double-blind, Placebocontrolled Study of Atrasentan in Patients with IgA Nephropathy at Risk of Progressive Loss of Renal Function | | | | |
| 2 | 210513 | 【JIRB】21-003-T-2 | 新案 初審 | 杜思德 Tu shih te |
| 瑞特連續血糖監測系統之有效性與安全性評估 Effectiveness and Safety Study of the Rightest Continuous Glucose Moring System | | | | |
| 3 | 150915 | 【CIRB】104CIRB07101 | 變更案第 13 次 初審 | 紀炳銓 Bin Chuan Ji |
| 一項第三期、開放性、隨機分配的試驗，針對完全切除之第 IB 期至第 IIIA 期非小細胞肺癌的患者，研究接受 CISPLATIN 為基礎的輔助性化療後使用 ATEZOLIZUMAB (抗-PD-L1 抗體) 相較於最佳支持性照護的療效與安全性 A PHASE III, OPEN-LABEL, RANDOMIZED STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF ATEZOLIZUMAB (ANTI-PD-L1 ANTIBODY) COMPARED WITH BEST SUPPORTIVE CARE FOLLOWING ADJUVANT CISPLATIN-BASED CHEMOTHERAPY IN PATIENTS WITH COMPLETELY RESECTED STAGE IB-IIIA NON-SMALL CELL LUNG CANCER | | | | |
| 4 | 190510 | 【CIRB】107CIRB2194 | 變更案第 5 次 初審 | 沈銘鏡 Ming Ching Shen |
| 一項第三期、開放性、單組試驗，評估接受第八凝血因子輸注預防用藥而殘存的第八凝血因子含量 ≤ 1 IU/dL 的 A 型血友病患者，使用腺相關病毒載體介導基因轉移人類第八凝血因子療法 BMN 270 的療效與安全性 A Phase 3 Open-Label, Single-Arm Study To Evaluate The Efficacy and Safety of BMN 270, an Adeno-Associated Virus Vector-Mediated Gene Transfer of Human Factor VIII in Hemophilia A Patients with Residual FVIII Levels ≤ 1 IU/dL Receiving Prophylactic FVIII Infusions | | | | |
| 5 | 200606 | 【CIRB】108CIRB12208 | 變更案第 4 次 初審 | 楊郁 Yu Yang |
| 以 efepoetin alfa 治療未接受透析之慢性腎臟病(ND-CKD)貧血患者之開放性隨機對照試驗。一項與 Methoxy Polyethylene Glycol-Epoetin Beta (Mircera)作比較的不劣性試驗 Open-label randomised controlled trial of Efepoetin Alfa for treatment of Anaemia associated with Chronic Kidney Disease Patients Not On Dialysis (ND-CKD). A non-inferiority trial compared to Methoxy Polyethylene Glycol-Epoetin Beta (Mircera) | | | | |
| 6 | 200804 | 【CIRB】109CIRB04065 | 變更案第 4 次 初審 | 陳清埤 Chen Ching Pei |

| | | | | |
|----|---|--------------------|-------------|---------------------|
| | <p>一項第三期、前瞻性、多中心、雙盲、隨機、平行分組試驗，用於比較 2 mg Pitavastatin/ 10 mg Ezetimibe 與 Pitavastatin 和 Ezetimibe 對於原發性高膽固醇血症或混合血脂異常患者的療效和安全性</p> <p>A Phase III, Prospective, Multi-center, Double-blind, Randomized, Parallel-Group Study to Compare the Efficacy and Safety of Pitavastatin 2 mg/ Ezetimibe 10 mg with Pitavastatin and Ezetimibe in Patients with Primary Hypercholesterolemia or Mixed Dyslipidemia</p> | | | |
| 7 | 200917 | 【CIRB】109CIRB07132 | 變更案第 1 次 初審 | 陳達人 DarRen Chen |
| | <p>一項針對先前至少 2 種化療方案治療失敗且具有荷爾蒙受體陽性 (HR+)/第 2 型人類表皮生長因子受體陰性 (HER2-) 之轉移性乳癌 (MBC) 受試者，比較 sacituzumab govitecan (IMMU-132) 和醫師所選治療 (TPC) 之第 3 期亞洲試驗</p> <p>A Phase 3 Asian Study of Sacituzumab Govitecan (IMMU-132) Versus Treatment of Physician's Choice (TPC) in subjects with Hormonal Receptor-Positive (HR+) Human Epidermal Growth Factor Receptor 2 Negative (HER2-) Metastatic Breast Cancer (MBC) who have failed at least two prior chemotherapy regimens</p> | | | |
| 8 | 201216 | 【CIRB】109CIRB10190 | 變更案第 1 次 初審 | 陳子和 TzeHo Chen |
| | <p>一項第三期、隨機、雙盲試驗，評估在併用輔助性化學治療的情況下(併用或不併用放射線治療)，Pembrolizumab 相較於安慰劑對於接受根治性目的手術後新診斷為高度風險子宮內膜癌的治療(KEYNOTE-B21 / ENGOT-en11 / GOG- 3053)。</p> <p>A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Adjuvant Chemotherapy With or Without Radiotherapy for the Treatment of Newly Diagnosed High-Risk Endometrial Cancer After Surgery With Curative Intent (KEYNOTE-B21 / ENGOT-en11 / GOG-3053).</p> | | | |
| 9 | 210214 | 【CIRB】109CIRB12234 | 變更案第 1 次 初審 | 賴冠銘 KuanMing Lai |
| | <p>一項 PAX-1 對於持續性癌症疼痛的止痛功效之探索性、隨機分組、雙盲、平行、安慰劑對照的 IIa 期臨床試驗</p> <p>An Exploratory, Randomised, Double-blind, Parallel-Group, Placebo-Controlled Phase IIa Study to Assess the Analgesic Activity of PAX-1 in Patients with Persistent Cancer Pain.</p> | | | |
| 10 | 210313 | 【CIRB】109CIRB10195 | 變更案第 1 次 初審 | 林炫聿 Hsuan Yu Lin |
| | <p>在患有初診斷之瀰漫性大 B 細胞淋巴瘤(DLBCL)且先前未治療的中高風險與高風險患者中，以 tafasitamab 加上 lenalidomide 併用 R-CHOP 相較於 R-CHOP 之療效及安全性的一項第三期、多中心、隨機、雙盲、安慰劑對照試驗</p> <p>A phase 3, multicenter, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of tafasitamab plus lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-intermediate and high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBCL)</p> | | | |