

2017 年第 10 次第二人體試驗委員會會議記錄

2017 year 10th-B IRB Meeting Minutes

- 一、日期 Date(YY/MM/DD)：2017 年 10 月 20 日（星期五）  
二、時間 Time：12:00-14:18  
三、地點 Location：福懋大樓四樓 人體試驗委員會暨行政中心會議室  
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)

- 陳彥宇(院內、醫療、醫師、男性)【IRB 150312 利益迴避 IRB 150312 Avoiding conflicts of interest】

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

- 倪淳淵(院內、醫療、醫師、女性)【IRB 150312 利益迴避 IRB 150312 Avoiding conflicts of interest】

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

- 蔡玉娟(院內、醫療、藥師、女性)【IRB 150312 利益迴避 IRB 150312 Avoiding conflicts of interest】

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

- 楊爵閣(院內、醫療、統計、男性)

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

- 李育霖(院內、醫療、醫師、男性)

Li, Yu-Lin ( 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 )

- 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<br>Medical Personnel      | 7  | 醫師(4)、藥師(1)、統計(1)、社會人士(1)<br>doctor (4) , Pharmacist (1) , Statistics (1), Member of society(1) |
| 非醫療<br>Nonmedical Personnel  | 4  | 社會人士(3)、法律(0)、病友團體代表(1)<br>Member of society (3) , Law(0), Patient group representative(1)      |
| 科學<br>Scientific member      | 7  | 醫師(4)、藥師(1)、統計(1)、社會人士(1)<br>doctor (4) , Pharmacist (1) , Statistics (1), Member of society(1) |
| 非科學<br>non-Scientific member | 4  | 社會人士(3)、法律(0)、病友團體代表(1)<br>Member of society (3) , Law(0), Patient group representative(1)      |
| 男<br>male                    | 7  | 院內(4)、院外(3)<br>Affiliation with Institution (5) , non-Affiliation with Institution (2)          |
| 女<br>female                  | 4  | 院內(3)、院外(1)<br>Affiliation with Institution (3) , non-Affiliation with Institution (1)          |

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)

- 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 )

缺 席 Absence：(職稱略 omit title)

記 錄 Recorder：洪翠霞 Hung, Tsui-Hsia

## 五、討論議案

| 主題                                   | 計畫名稱              | 決議    |
|--------------------------------------|-------------------|-------|
| 編號：170812<br>【新案 複審第 1 次】<br>主持人：陳堯俐 | 抑制肝癌細胞生長之嶄新抗癌藥物研發 | 修正後複審 |
| 編號：171004                            | 台灣骨髓增殖惡性病登錄計畫     | 修正後提會 |

|   |   |         |
|---|---|---------|
| 【新案】<br>主持人：林炫聿                               |   |         |
| 編號：140714<br>【變更案第 5 次】<br>主持人：陳守棟            | 一項針對患有初期三重陰性乳癌 (TNBC) 受試者，以評估增添 Veliparib 加 Carboplatin 於標準前導性化療相較於增添 Carboplatin 至標準前導性化療相較於標準前導性化療的安全性與療效之隨機分配、安慰劑對照、雙盲、第 3 期試驗 | 核准      |
| 編號：120607<br>【期中報告第 5 次】<br>主持人：林慶雄           | 基因-環境交互作用誘發氣喘及過敏性疾病之研究  | 修正後複審   |
| 編號：130810<br>【期中報告第 4 次】<br>主持人：陳守棟           | 針對正常及抗化療藥物的 MCF-7 乳癌細胞株在氧化壓力下粒線體損傷與氧化壓力變化之研究探討  | 修正後複審   |
| 編號：140801<br>【期中報告第 3 次】<br>主持人：林慶雄           | 慢性阻塞性肺病臨床試驗合作聯盟與生物檢體資料收集及分析   | 修正後複審   |
| 編號：151011<br>【期中報告第 2 次】<br>主持人：林屏沂           | 探討影響腫瘤指標(胎兒球蛋白及異常凝血原)於肝癌診斷準確度之臨床因子  | 核准      |
| 編號：151119<br>【期中報告第 2 次】<br>主持人：蘇維文           | 慢性 B 型肝炎接受核苷酸類似物治療後之追蹤研究  | 修正後複審   |
| 編號：160708<br>【期中報告第 1 次<br>複審第 1 次】<br>主持人：陳明 | 利用次世代定序對聽力障礙病人進行遺傳分析  | 核准      |
| 編號：161001<br>【期中報告第 1 次】<br>主持人：林炫聿           | Lipo-ABR (amphotericin B)用於嗜中性白血球低下持續發燒病患之上市後藥品監測研究。  | 修正後複審   |
| 編號：150312<br>【實地訪視第 1 次】<br>主持人：邱足滿           | 藥物過敏反應之免疫機轉及基因體研究   | 書面說明後提會 |