

2018 年第 2 次第二人體試驗委員會會議記錄

2018 year 2nd-B IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2018 年 02 月 23 日（星期五）

二、時間 Time：12:00-12:57

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) 【IRB151228 利益迴避-PI 為同部門醫師 IRB 151228
Avoiding conflicts of interest】

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)

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

■ 倪淳淵(院內、醫療、醫師、女性)

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

■ 蔡玉娟(院內、醫療、藥師、女性)

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)

■ 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	4	社會人士(2)、法律(1)、病友團體代表(1) Member of society (2) , 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	4	社會人士(2)、法律(1)、病友團體代表(1) Member of society (2) , Law(1), Patient group representative(1)
男 male	6	院內(4)、院外(2) Affiliation with Institution (5) , non-Affiliation with Institution (1)
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)

- 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)

- 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)

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：171104 【新案 複審第 2 次】 主持人：蘇維文	慢性C型肝炎接受新型直接抗病毒藥物治療後之追蹤研究	核准
編號：140111 【期中報告第 4 次】 主持人：邱瑩明	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	核准
編號：151228 【期中報告第 2 次】 主持人：劉嘉鴻	肝細胞癌與肝內膽道癌中活性氧分子基因表現與肝炎病毒感染的相關性研究	核准
編號：161208	先天性免疫細胞次族群與調節B細胞於紅斑性狼瘡病患	核准

【期中報告第 1 次】 主持人：蔡易晉	之免疫調節機轉研究	
編號：161203 【不遵從事件】 201801-8 主持人：邱瑩明	一項隨機分配、雙盲、安慰劑和活性藥物對照、多中心、第三期試驗，在罹患中至重度活動性類風濕性關節炎，且對 Methotrexate 療效反應不足的受試者中，評估 Filgotinib 與 Methotrexate 併用 52 週的療效及安全性	存查，同意試驗繼續進行