

2018 年第 4 次第三人體試驗委員會會議記錄

2018 year 4th-C IRB Meeting Minutes

- 一、日期 Date(YY/MM/DD)：2018 年 04 月 26 日（星期四）
二、時間 Time：12:00-12:43
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：

蘇矢立（院內、醫療、醫師、男性）

Su, Shih-Li (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

出席人員 Attendant：(職稱略 omit title)

- 張櫻霖（院內、醫療、醫師、男性）

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

- 高峻凱（院內、醫療、醫師、男性）【熟稔易受傷害族群-5-18 歲未成年人委員，小兒科醫師】

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

- 蕭品卉（院內、醫療、醫師、女性）

Hsiao, Yi-Hsuan (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-5-18 歲未成年人委員，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)

- 陳志洺（院外、非醫療、社會公正人士、男性）

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

- 尤正亮 (院外、非醫療、社會公正人士、男性)

Yu, Cheng-Liang (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, male)

- 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	7	醫師(4)、藥師(1)、統計(2) Doctor (4), Pharmacist (1), Statistics (2)
非科學 non-Scientific member	5	社工(1)、法律(1)、社會公正人士(3) Social Worker (1), Law (1), Member of society (3)
男 Male	7	院內(4)、院外(3) Affiliation with Institution (4), non-Affiliation with Institution (3)
女 Female	5	院內(3)、院外(2) Affiliation with Institution (3), non-Affiliation with Institution (2)

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、討論議案

主題	計畫名稱	決議
編號：180406 【新案】 主持人：吳怡磊	景岳益生菌對於血脂過高之體重過重或肥胖兒童和青少年之臨床症狀改善效益	修正後提會
編號：160602 【期中報告第 2 次】 主持人：林楷煌	多中心、雙盲、隨機分配、平行分組、安慰劑對照之第三期樞紐臨床試驗，以評估敗血症與敗血性休克病人使用瑞克西(RexisR)作為輔助治療之療效與安全性	修正後複審

編號：170516 【期中報告第 1 次】 主持人：王文甫	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 CRENEZUMAB 使用於前驅期至輕度阿茲海默症病患的療效和安全性試驗	修正後複審
編號：140205 【實地訪視第 1 次】 主持人：林淑惠	EGFR 基因突變與抗氧化基因核甘酸多形性在台灣非小細胞肺癌病人的相關性研究	書面說明後複審
編號：150117 【實地訪視第 1 次】 主持人：林晏任	到院前心跳停止存活病人生理與心理健康之研究	書面說明後複審