

2020 年第 07 次第二人體試驗委員會會議記錄

2020 year 07th-B IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2020 年 07 月 24 日（星期五）

二、時間 Time：12:00-14:00

三、地點 Location：福懋大樓 B1 尊榮 B 廳

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)

■ 陳琬青(院內、醫療、醫師、女性)

Chen, Wan-Chin ( Affiliation with Institution, Medical Personnel ( Scientific member ), doctor, female )

■ 楊淵博(院內、醫療、醫師、男性)【IRB160804 利益迴避- PI 為同部門醫師 IRB 160804 Avoiding conflicts of interest- Physician of the same department】

Yang, Yuan-Po ( Affiliation with Institution, Medical Personnel ( Scientific member ), doctor, male )

■ 蔡玉娟(院內、醫療、藥師、女性)

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

■ 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 )

■ 劉柏毅(院內、醫療、醫師、男性)

Liu, Po-I ( 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 )

■ 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(4)、藥師(1)、統計(0)、社會人士(1) doctor (4) , Pharmacist (1) , Statistics (0), 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(4)、藥師(1)、統計(0)、社會人士(1) doctor (4) , Pharmacist (1) , Statistics (0), 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	6	院內(3)、院外(3) Affiliation with Institution (4) , non-Affiliation with Institution (2)
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)

- 楊爵閣(院內、醫療、統計、男性)

Yang, Chueh Ko ( Affiliation with Institution, Medical Personnel ( Scientific member ), statistics, 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：200504 【新案 複審第 1 次】 主持人：陳郁菁	建立人類胚胎幹細胞株	核准
編號：200605 【新案 複審第 1 次】 主持人：陳堯俐	探討代謝與免疫基因表達與肝癌臨床因子的相關性研究	修正後複審

編號：200616 <b>【新案】</b> 主持人：蘇維文	一項隨機分配、開放性、多中心的第 III 期臨床試驗，評估 Toripalimab (JS001) 併用 Bevacizumab 相較於 Sorafenib 作為晚期肝細胞癌(HCC)第一線治療的安全性和療效	修正後提會
編號：200705 <b>【新案】</b> 主持人：邱南英	鬱症病人認知功能評估問卷的發展	修正後複審
編號：190814 <b>【變更案第 2 次 複審第 1 次】</b> 主持人：顏旭亨	困難消化道病變之診斷及治療: 單一中心之經驗	核准
編號：160804 <b>【期中報告第 4 次】</b> 主持人：黃靜惠	血中白血球粒線體 DNA 拷貝數和急性心肌梗塞後左心室的球形指標之探討	核准
編號：190310 <b>【不遵從事件】</b> 202007-4 主持人：陳達人	一項針對荷爾蒙受體陽性、HER2 陰性的早期乳癌患者，評估 ribociclib 加上內分泌療法作為輔助治療的療效與安全性之第三期、多中心、隨機分配、開放性試驗 (以 Ribociclib 作為新輔助治療的試驗 [LEE011]: NATALEE)	存查，同意試驗繼續進行