高雄醫學大學附設中和紀念醫院
Kaohsiung Medical University Chung-Ho Memorial Hospital
人體試驗審查委員會
Institutional Review Board

807高雄市三民區自由一路100號
No. 100, Tzyou 1st Road, Kaohsiung 807, Taiwan
TEL： 886-7-3121101 ext.6646、886-7-3133525
FAX： 886-7-3221408

人體研究新案同意證明書

計畫中文名稱：澎湖監獄受刑人族群B、C、D型肝炎之流行病學研究
計畫主持人：謝孟軒
共同及協同主持人：余明隆、呂明穎、陳桂英、蔡佩倩、陳軍廷
機構名稱：高雄醫學大學附設中和紀念醫院
經費來源：自籌
IRB 編號：KMUHIRB-SV(I)-20190033
核准日期(審查通過日)：2019 年 5 月 17 日
計畫執行期間：自 2019 年 5 月 17 日至 2020 年 12 月 31 日止
計畫書：第一版，2019/5/17
受試者同意書：第一版，2019/5/17
問卷：第一版，2019/5/17

未預期事件或藥品嚴重不良反應通報、後續定期追蹤之程序及應注意事項，請參閱背面。

高雄醫學大學附設中和紀念醫院
第一人體試驗審查委員會
主任委員：顏學偉

西元 2019 年 5 月 17 日

Approval of Clinical Trial/Research

Protocol Title: The epidemiology of hepatitis B 、C 、D in the inmates of Penghu Prison.
Principal Investigator(s): Meng-Hsuan Hsieh
Co_Investigator(s): Ming-Lung Yu 、Ming-Ying Lu 、Guei-Ying Chen 、Pei-Chien Tsai 、Chun-Ting,Chen ,
Institution: Kaohsiung Medical University Chung-Ho Memorial Hospital
Source of Funding: Self-financing
IRB Number:KMUHIRB-SV(I)-20190033
Approval dated: 2019/5/17
Duration of Approval: from 2019/5/17 to 2020/13/21
Protocol：Version 1, 2019/5/17
Informed Consent Form：Version 1, 2019/5/17
Questionnair：Version 1, 2019/5/17

See the back of this page for the procedures for reporting unanticipated problems, or drug serious adverse reactions, or interim, and other important notes.

Hsueh-Wei Yen

Hsueh-Wei Yen, MD
Chairman
Institutional Review Board- I
Kaohsiung Medical University
Chung-Ho Memorial Hospital

Kaohsiung Medical University Institutional Review Board Chung-Ho Memorial Hospital

未預期事件通報、後續定期追蹤之程序及應注意事項

本會組織與執行皆符合 ICH-GCP

The Institutional Review Board performs its functions according to written Operating procedures and complies with ICH-GCP and with the applicable regulations.

1.院內受試者發生死亡或危及生命案例應該在獲知日起七日以內通報本委員會，其他非預期嚴重藥品不良反應應於十五日以內向本委員會通報。

2.可能危害受試者安全、影響試驗執行之新發現或影響人體試驗委員會同意試驗繼續進行之新發現，須向本委員會報告。

3.請於有效期限到期二個月前繳交期中報告至本會審查。期中報告繳交日期：西元2020年5月16日前。核准有效期限屆滿，若尚未通過期中報告追蹤審查，不得繼續試驗。計畫主持人，未依規定繳交期中報告，本會得暫停審查受理中的計劃文件，且不受理其新申請案。

4.結案報告：試驗完成後，應將執行情形及結果以書面報告本會核備。

5.暫停或終止計畫報告：計畫完成前就暫停或停止收案與追蹤，應與書面「計畫暫停或終止摘要表」，送交本會核備。

6.嚴重或持續不配合本委員會規範，未能遵循以上事項，可能導致您的研究計畫暫停或永久終止，並影響您未來送審計畫的權益。

Procedures for reporting Unanticipated Problems , or interim, and other important notes:

1. If subject(s) die(s) or hospitalized, IRB should be notified within 7 days of becoming aware of this. For other unexpected serious adverse drug reactions, IRB should be notified within 15 days.
2. If any new findings affect the safety of the participants or others, or the implementation of the study or decision of IRB as to allow to continuing of the study, IRB should be informed promptly.
3. Please provide us your Interim report two months before the dead line of Duration of Approval. An interim report should be submitted by 2020/5/16. If the interim report has not been submitted by the deadline, the study must be halted. If a principal investigator fails to submit an interim report on schedule, IRB may suspend review of other protocols submitted by the investigator, and may refuse to review any further applications made by the investigator.
4. Final report: When the study has been completed, details of the study implementation and of the results obtained should be submitted to IRB in writing for review.
5. For any reason, the study is terminated prior to the completion of a study. The summary report should be submitted to IRB.
6. Serious or repeated failure to comply with regulations and with the above requirements may result in the study being suspended or terminated, and may affect you to submit studies for review in the future.