Approval of Clinical Trial/Research

Protocol Title: The impact of differential cytokine expression between interferon and direct-acting antiviral agents on hepatic carcinogenesis in chronic hepatitis C patients

Principal Investigator(s): Ming-Lung Yu
Co_Investigator(s): Ming-Ying Lu, Shu-Chi Wang
Institution: Kaohsiung Medical University Chung-Ho Memorial Hospital
Source of Funding: Self-financing
IRB Number: KMUHIRB-E(I)-20180307
Approval dated: 2018/11/29
Duration of Approval: from 2018/11/29 to 2021/12/31
Initial Review Application Form: Version 1, 2018/9/1
Waiver of Informed Consent Form: Version 1, 2018/11/29

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
MD
Chairman
Institutional Review Board-I
Kaohsiung Medical University
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. 請於有效期滿前二個月前繳交期中報告至本會審查。（期中報告繳交期限：西元2019年11月28日）。若
核准有效期滿後，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 2019/11/28. 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.
Approval of Clinical Trial/Research

Protocol Title: The cytokine and gene expression induced by peginterferon and direct-acting antiviral agents in chronic hepatitis C patients
Approval dated: 2017-8th-IRB(II) 2017/8/29
IRB Number: KMUHIRB-G(II)-20170020
Trial/Research Institution: Kaohsiung Medical University Chung-Ho Memorial Hospital
Study duration: Since IRB Approved by date until 2020/12/31.
Principal Investigator: Ming-Lung Yu
Co-principal Investigator: Wan-Long Chuang
Co-Investigator: Chia-Yen Dai, Jee-Fu Huang, Chung-Feng Huang, Ming-Lun Yeh

Above clinical research is approved by the Institutional Review Board-II on 2017/8/29 and valid till 2018/8/28. The constitution and operation of this review board are according to the guidelines of GCP. According to GCP, IRB-II will have to review each clinical research case annually and decide whether continue it or not. Therefore, please send us your Annual Report two months before the expiry date.

Sincerely yours,

Li-Tzong Chen

Dr. Li-Tzong Chen, MD, PhD
Chairman
Institutional Review Board-II
Kaohsiung Medical University
Chung-Ho Memorial Hospital