人體研究新案/變更案/期中報告同意證明書

計畫中文名稱：

計畫主持人：（中文名字） / 共 同 及 協同主持人：（中文名字）

機構名稱：

廠商名稱：

計畫編號：

本會編號： / KMUHIRB- F/E/G/SV(I/II)-YYYY○○○○

會議日期： (若為簡易審查案件，不須列上會議日期)

核准日期(審查通過日)：YYYY-○ th-IRB(I/II) YYYY/MM/DD

計畫執行期間：自 IRB 審查通過日起至西元 OOOO 年 OO 月 OO 日

計畫書：(版本、日期)

受試者同意書：(版本、日期)

個案報告表：(版本、日期)

主持人手冊：(版本、日期)

問卷：(版本、日期)

廣告：(版本、日期)

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。

Approval of Clinical Trials/Research
(New Applications/Amendments/Interim Reports)

Protocol Title:

Principal Investigator(s):（英文名字） /Co_Investigator(s): （英文名字）

Institution:

Sponsor:

Protocol Number: /IRB Number: KMUHIRB-F/E/G/SV(I/II)-YYYY○○○○

Board Meeting：(若為簡易審查案件，不須列上會議日期)

Approval dated: YYYY-○ th-IRB(I/II) YYYY/MM/DD

Duration of Approval: from Month / Day / Year to Month / Day / Year

Protocol：Version , Date

Informed Consent：Version , Date

Case Report：Version , Date

Investigator's Brochure：Version , Date

Questionnair：Version , Date

Advertisement：Version , Date

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

高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

第一/二人體試驗審查委員會 Institutional Review Board Ⅰ/ II

主任委員 Chairman：（中文名字 signature，日期 date）

Hsueh-Wei Yen, MD/ Li-Tzong Chen, MD, PhD

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 xxxx 年 xx 月 xx 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 (Day/Month/Year). 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.