1.目的 Purpose

人體試驗委員會(以下簡稱人委會)爲達成受試者保護，需對研究計畫進行風險及潛在利益評估，以保護受試者及確保審查及監督品質、並即時發現問題，採取有效控制措施之風險管理及利益評估程序指引。

To achieve subject protection, the Institutional Review Board (hereinafter referred to as "IRB") is required to perform risks and potential benefits assessments on the study protocol in order to protect the subjects and ensure the quality of review and surveillance, uncover problems promptly and thus take effective control measures as the guidelines for risk management and benefit assessment procedures.

2.適用範圍 Scope

根據 ICH Q9 風險管理的應用，凡人委會運作過程中與風險管理及利益評估有關之組織、人員、活動、作業與文件均屬於本程序之範疇。

According to the applications of ICH Q9 risk management, all organizations, personnel, activities, operations and files that are related to risk management and benefit assessment during the operation of the IRB, are within the scope.

3.參考文件 References

3.1 ICH Q9風險管理的應用程序

ICH Q9 Risk Management Application Procedures

3.2 AAHRPP基準 (2016年1月)

AAHRPP Standards (January 2016)

3.3 國際醫藥品稽查協約組織之藥品優良製造指引（第一部、附則）

PIC/S：Guide to Good Manufacturing Practice for Medicinal Products（Part I、Annexes）PE009-9 (1 September 2009) © PIC/S September 2009

4.名詞定義 Terminology

5.作業內容 Scope of operation

5.1 職責 Responsibilities

5.1.1 審查委員：對新案風險及潛在利益之評估依據新案初審審查意見表提供建議(附件一)。

Reviewers: can provide recommendations toward the assessments of risks and potential benefits in the new cases based on new application initial review comment form (Attachment 1).

5.1.2 主任委員：完成審查會中新案審查之最終整體風險及利益評估。

Committee director: shall complete the final and comprehensive risk and benefit assessment in the new case review.

5.1.3 計畫主持人：對研究計畫案之風險及潛在利益，需事先評估。

Principal Investigator: shall perform assessments on the risks and potential benefits of the study in advance.

5.2 細則 Rules

5.2.1 行政人員備妥新案初審審查意見表給予初審委員，根據有關「研究結果可獲得新知識，且考量受試者之權利及福祉後值得讓受試者/群體之冒此風險的分類」之評估意見：

The administrative staff will prepare new application initial review comments form to the initial reviewers. The assessment comments will be made in accordance with “The study results can bring novel knowledge; and after considering the rights and welfare of the subjects, which deserves to put the subjects/population into a risk category”:

A.相當於最小風險(第一類風險) ，最小風險指預計研究對受試者/群體造成的傷害或不適及嚴重程度，不會超過在日常生活、例行身體檢查所遭遇者。

Equal to minimal risk (Class I risk): minimal risk refers to studies that are expected to cause damages or discomfort to the subjects/population, but the severity will not exceed the risks that encounter in daily living or routine physical examinations.

B.超過最小風險，但對受試者/群體有直接利益(第二類風險)

Over minimal risks, but benefit the subjects/population directly (Class II risk)

C.超過最小風險，但對受試者/群體無直接利益，但有助於瞭解受試者之情況(第三類風險)

Over minimal risks without benefiting the subjects/population directly, but is helpful to understand the situations of the subjects (Class III risk)

D.超過最小風險，且對受試者/群體無直接利益，但研究主題可得到價值之結果(第四類風險)

Over minimal risks without benefiting the subjects/population directly, but the study topic can obtain valuable results (Class IV risk)

5.2.2 審查委員/諮詢專家依上述狀況評估風險之高低，並勾選建議追蹤頻率（每季、半年或一年），提審查會議討論並做出決議。

The reviewers/consultant experts will assess the level of risks based on the

above mentioned conditions, select recommended follow-up frequency (every season, half year or a year), and send to the review meeting for discussion and make resolutions.

5.2.3 承辦人員依審查委員建議及審議會之決議，提供風險因子、可能導致的事故及現有控制措施等供計畫主持人參考改進。

The managing officer will provide risk factors, potential accidents and existing control measures to the Principal Investigator for reference and improvement based on the recommendations of the reviewers and the resolutions of the review meeting.

5.3 案件監督：Case monitoring:

5.3.1 審查委員對已核准進行中之計畫案件進行風險及利益評估，若發現人體研究及試驗計畫執行期間有潛在異常之狀況，可能會影響受試者之權利及福祉時，應立即向執行秘書報告並做出預防性之建議。

The reviewers has conducted risk and benefit assessment for the studies approved for implementation. If any potential aberrant situations are found during the human study and study period that may affect subject’s rights and welfare, it is required to report to the executive secretary and make preventive recommendations.

5.3.2 執行秘書就異常狀況予以分析，如有潛在異常狀況，應督促行政人員，通知試驗委託者及計畫主持人，提出預防措施，以避免影響受試者之權利及福祉。

The executive secretary shall analyze aberrant situations. For any potential aberrant situation, the secretary shall urge the administrative staff to inform

the Sponsor and Principal Investigator to propose preventive measures in order to avoid affecting the rights and welfare of the subjects.

5.3.3 行政人員將委員風險評估結果及建議改善措施提至人委會審查會議討論，依會議決議執行。

The administrative staff will send the risk assessment results and recommended improvement measures to the IRB review meeting for discussion so that the IRB may perform in accordance with the meeting resolutions.

5.3.4 風險及利益評估視需要於審查會議回顧事件之處置情形，以確認風險仍在控制中，並安排進行實地查核。

Risk and benefit assessment shall handle events review in the meeting based on necessity to confirm whether the risks are still under control in order to arrange field inspection.

5.4 文件歸檔：所產生之各項紀錄及文件，依人委會作業程序辦理。

File archiving: All generated records and files shall be processed in accordance with IRB operational procedures.

6.附件 Attachment

6.1 附件一(KMUH/IRB/AF/3.1-01/11.0)新案初審審查意見表

Attachment 1 (KMUH/IRB/AF/3.1-01/11.0) New Application Initial Review Comment Form