1.目的 Purpose

為確保於本院核准之人體研究計畫之執行，符合行政院衛生福利部「人體研究法」之規定，藉由定期內部稽核、實地訪查執行計畫之進行，以協助、督導及考核各計畫相關單位人體研究之實際運作情形，以確保人體研究執行品質，及保護受試者之權益。

To ensure the implementation of the human studies approved by KMUHIRB has met the regulations of "Human Subjects Research Act" promulgated by MOHW, Executive Yuan, routine internal audit and site visit will be conducted to facilitate, supervise and inspect the actual operation of the human studies in relevant units. The quality of human study implementation and the rights of the subjects will thereby be protected.

2. 適用範圍 Scope

本章節適用於所有於本院核准之人體研究計畫，具顯著超過最小風險、執行偏差或被申訴檢舉之人體研究計劃，列為優先稽核訪查對象，其他人體研究計畫案得定期進行計畫稽核。稽核/訪視分為頻率性查核、有因性查核兩大類。一般審查研究計畫案、特殊族群及易受傷害族群委託臨床試驗管理委員會（CTMC）進行定期計畫稽核，並將稽核結果於時限內通報本會，由該案件承辦人員將相關資料提報委員會備查或討論，以確保該計畫之執行可符合藥品優良臨床試驗準則(GCP)之規定。

This section is applicable to all human studies approved by KMUHIRB. Human studies with significant increase over minimal risks, execution biases or human studies reported for appeals will be listed as the prioritized audit/inspection target. Other human studies may be audited regularly. The audit/inspection can be

divided into two major types including inspections with certain frequency and reasons. Regular review studies and special/vulnerable population studies will be commissioned to the CTMC for routine audit, the audit results will be reported to the IRB within limited time frame. The managing officer of the case will then submit relevant materials to the IRB for review or discussion for reference to ensure the implementation of the study has met the regulations of GCP.

3.參考文件 References

3.1 人體研究法(2011年12月)

Human Subjects Research Act (December 2011)

3.2 人體試驗管理辦法(2009年12月)

Regulations on Human Trials (December 2009)

3.3 藥品優良臨床試驗準則(2014年10月)

Guidelines of Good Clinical Practice (October 2014)

3.4 醫療器材優良試驗基準 (2007年5月)

Guidelines of Good Clinical Practice on Medical Devices (May 2007)

3.5 人體研究倫理查核審查委員會組織及運作管理辦法 (2012年8月)

Regulations Governing the Organization and Operational Management of the Institutional Review and Advisory Board for Human Subject Research (August 2012)

3.6 赫爾辛基宣言 (2000年10月)

The Declaration of Helsinki (October, 2000)

3.7 臨床試驗管理委員會（CTMC）標準作業程序書

CTMC SOP

3.8 醫療機構人體試驗委員會組織及作業基準（2003年11月）

The Organization and Operating Standards of the Institutional Review Board of the Medical Institutes (November 2003)

3.9 藥品優良臨床試驗準則（2005年1月）

Guidelines of Good Clinical Practice (January 2005)

3.10 高雄醫學大學附設中和紀念醫院 臨床試驗管理委員會 標準作業程序 V5.2

KMUH CTMC SOP V5.2

4.名詞定義 Terminology

4.1 實地訪查：對研究試驗活動及文件之獨立有系統的檢查，目的是判定有關計畫審查和通過、研究數據在收集及通報等作業過程，是否依照標準作業程序、優良臨床試驗規範、赫爾辛基宣言及相關法規的要求。

Site visit: refers to the independent and systemic examination on study activities and documents. The purpose is to determine whether the operational process such as study review, approval, the collection of study data and report have met the requirements of SOPs, GCP, the Declaration of Helsinki and relevant laws and provisions.

4.1.1 一般案及特殊/易受傷害族群計畫案則委由臨床試驗管理委員會(CTMC)定期稽核。

The regular and special vulnerable population studies will be audited regularly by the CTMC.

4.2 執行偏差：此指由人委會定期評估時，發現其研究計畫未依規定經審查會通過或主管機關核可，自行變更人體研究內容。

Execution bias: refers to the self-amended human study contents without being approved by the IRB or authorized by the competent authorities, but discovered by the IRB during routine assessments.

4.3 有因性查核為研究計畫有下列情形之一時得進行實地訪查：

Site visit is required when one of the following situations occurs in the study inspection with reasons:

4.5.1 足以影響研究對象權益、安全、福祉之情事。

Events that are sufficient to affect the rights, safety and welfare of the subjects occur.

4.5.2 研究對象發生嚴重不良事件或反應。

Subjects have SAEs or ADRs.

4.5.3 出現影響計畫風險利益評估之重要事件或資訊。

Significant events or information that may affect the assessment of risks and benefits of the study occur.

4.5.4. 出現執行偏差之事件。

Execution bias occurs.

4.5.5 期中/結案報告受試者同意書稽核出現缺失。

Defects occur in the audit of subject ICF reported in the interim/final report.

5.作業內容 Scope of operation

5.1 流程 Process

程序 Procedure	權責 Rights and responsibilities	相關文件 Related documents
提供稽核/實地訪查單計畫案 Provide the list of studies with audit/Site visits	行政秘書/研究助理 Administrative secretary/Research assistant	實地訪查計畫案名單 The list of members participating in the site visit
指定稽核/實地訪查委員 Appoint audit/Site visit members	主任委員 Committee director	計劃案資料 委員名單 Study materials List of members
執行稽核/實地訪查 Conduct audit/Site visits	委員/執行秘書/行政秘書/研究助理 Committee member/ Executive secretary/Administrative secretary/Research assistant	稽核紀錄表 實地訪查表 Audit record Site visit record
彙整稽核/實地訪查結果 Summarize the audit/Site visit results	行政秘書/研究助理 Administrative secretary/Research assistant	稽核/實地訪查結果彙整表 The summary table of audit/Site visit results
提報委員會決議 Report to the Committee for resolution	人委會 IRB	會議記錄 Meeting minutes
通知稽核/實地訪查結果決議 Inform the resolutions of audit/Site visit results	行政秘書/研究助理 Administrative secretary/Research assistant	人體研究實地訪查決議通知 Human research site visit resolution notification
紀錄保存 Record retention	行政秘書 Administrative secretary	

5.2職責Responsibilities

5.2.1 主任委員：指定工作人員進行實地訪查，核定訪查結果。

Committee director: appoints staff to conduct site visits and review and approve visit results.

5.2.2 委員：進行實地訪查。

Committee member: conduct site visits.

5.2.3 執行秘書：決定實地訪查案件並進行實地訪查。

Executive secretary: decide site visit cases and conduct site visits.

5.2.4 行政秘書：提供具顯著超過最小風險、執行偏差、期中/結案報告受試者同意書稽核缺失或被申訴檢舉之人體研究計畫，配合委員進行實地訪查，彙整訪查結果。

Administrative secretary: provides the significant increase over minimal risks, execution bias, interim/final report defects of the subject ICF or the reported human studies to help the IRB members to conduct site visits and summarize visit results.

5.2.5 臨床試驗管理委員會(CTMC)：一般案及特殊/易受傷害族群計畫案，定期進行實地訪查稽核。

Clinical Trial Management Committee (CTMC): responsible for regular and special/vulnerable population studies and conducts regular field inspections and audit.

5.3 定期審查 Regular review

5.3.1 計畫主持人、協同主持人及其他執行之研究團隊應具資格。

The qualification of the PI, co-investigator and other members in the study implementation team.

5.3.1.1 依醫療法第八條之計畫案或具侵入性或具危險性之臨床試驗計劃，計畫主持人須具六年曾受三十小時人體相關訓練；體細胞或基因治療人體試驗之主持人，另加五小時以上之有關訓練，及六年研習醫學倫理相關課程九小時以上。協同主持人三年曾接受九小時以上人體相關訓練及研習醫學倫理相關課程。其他執行之研究團隊三年曾接受過一次以上之人體相關訓練及研習醫學倫理相關課程。

According to the Medical Care Act Article 8 or invasive or dangerous clinical trials, the PI must receive 30 hours of human study-related training within 6 years. For the PIs of somatic cells or gene therapy human studies, they must receive additional at least 5 hours of related training and at least 9 hours of medical ethics training within 6 years. For co-investigators, they must receive at least 9 hours of human study-related training and medical ethics-related training within 3 years. For the members in other study implementation teams, they must receive at least once human study-related training and medical ethics-related training within 3 years.

5.3.1.2 凡計畫案內容符合簡易計畫案條件，因衛生署規定改列一般案之基因相關與特殊族群及易受傷害族群之計畫案，計畫主持人及協

同主持人三年曾接受九小時以上人體相關訓練及研習醫學倫理相關課程。For studies that meet expedited review, because they have been reclassified as regular gene-related and special population as well as vulnerable population studies according to the regulations promulgated by MOHW, the PI and sub-investigators shall receive at least 9 hours of human study-related training and medical ethics-related training within 3 years.

5.3.1.3 人委會審核通過進行中之計畫案每年應提出期中報告至人委會審查。

For studies that have been approved by the IRB for implementation, the interim report shall be submitted annually to the IRB for review.

5.3.1.4 人委會審核通過之計畫案於結案後 3 個月內應提出結案報告至人委會審查。

The studies reviewed and approved by the IRB shall submit the final reports to the IRB for review within 3 months after the study has been completed.

5.4 計畫稽核及實地訪查

Study audit and site visit

5.4.1 符合醫療法第八條或具侵入性或具危險性之臨床試驗計劃皆納入「臨床試驗管理委員會」管理，進行定期追蹤、定期稽核及實地訪查，每件計畫案每年至少進行 1 次計畫稽核。

For clinical studies that meet Medical Care Act Article 8 or are invasive or

dangerous shall be subject to the "CTMC" for regular follow-up, routine audit and site visits. Each study shall be audited at least once annually.

5.4.2 臨床試驗計畫發生重大不良影響、試驗偏差偏離、受試者為特殊族群或易受傷害族群及其他經審查會議認定需進行稽核者，亦納入「臨床試驗管理委員會」管理，進行定期追蹤、定期稽核及實地訪查。

For clinical studies that are considered requiring being audited by the review meeting due to the occurrence of significant adverse influences, study biases/deviations/, having subjects that are special population or vulnerable subjects, or other reasons, they shall be subject to the "CTMC" as well for regular follow-up, routine audit and site visits.

5.4.3 人委會於審查會議時，審查「臨床試驗管理委員會」通報之臨床試驗之重大缺失及持續未改善之中度缺失，複查後並決議後續處理方式

The IRB will review the major defects of the clinical trials reported by the "CTMC" and the moderate defects that have not been improved during the review meeting. The subsequent handling approaches will be decided after secondary review.

5.4.3.1 計畫主持人應於審查會議前書面回覆「臨床試驗管理委員會」審查之缺失及處理方式。

The PI shall respond to the defects and handling approaches to the "CTMC" in writing before the review meeting.

5.4.3.2 人委會得要求計畫主持人列席審查會議報告缺失及處理方式。

The IRB may ask the PI to attend the review meeting to report defects and corresponding handling approaches.

5.4.3.3 人委會決議後續處理方式包括「臨床試驗管理委員會」加強稽核及中止/終止臨床試驗。

The IRB will decide the subsequent handling approaches including the "CTMC" will reinforce auditing and discontinuing/terminating clinical studies.

5.5 有因性實地訪查流程

The process of site visit with reasons

5.5.1 行政秘書提供具顯著超過最小風險、執行偏差、期中/結案報告缺失或被申訴檢舉之人體研究計畫清單。

The administrative secretary will provide the significant increase over minimal risks, execution bias, interim/final report defects or the reported human study list of the PI.

5.5.2 主任委員決定實地訪查案件，指定工作人員進行實地訪查。並於訪查前發文通知受訪查之計畫主持人。

The committee director will decide site visit cases, appoint staffs to perform site visits, and issue an official letter to inform the PI about the visit before the site visit.

5.5.3 由執行秘書、委員、行政秘書依「實地訪查表」進行實地訪查，有因性/實地訪查依每季計畫案件申請比例稽核。

The executive secretary, members and administrative secretary will conduct site visits in accordance with "site visit form".

5.5.4 行政秘書彙整訪查結果。

The administrative secretary will summarize the visit results.

5.5.5 於行政會議中檢視訪查評論與建議，並討論實地訪查之結果。

Review the visit comments and suggestions during the administrative meeting, and discuss the results of the site visit.

5.5.6 主任委員核定訪查結果，並將審查會決議資料回覆予計畫主持人與試驗委託者。

The committee director will review and approve the visit results and send the meeting resolution to the PI and Sponsor as responses.

5.5.7 訪查結果之審查會議報告歸檔於實地訪查檔案中。

The visit results of the meeting report will be archived in the site visit files.

6.附件 Attachment

6.1 附件一(KMUH/IRB/AF/3.7-01/11.0) 人體研究實地訪查表

Attachment 1 (KMUH/IRB/AF/3.7-01/11.0) IRB Site Visit Form

6.2 附件二(KMUH/IRB/AF/3.7-01/11.0) 人體研究實地訪查結果彙整表

Attachment 2 (KMUH/IRB/AF/3.7-01/11.0) IRB Site Visit Result Summary Table

6.3 附件三(KMUH/IRB/AF/3.7-01/11.0) 人體研究實地訪查決議通知

Attachment 3 (KMUH/IRB/AF/3.7-01/11.0) IRB Site Visit Resolution Notification